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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Report of the Workgroup on E-Pedigree

William Powers, Public Member, Chair
Stan Goldenberg, RP.h.

Report of June 20, 2006

FOR ACTION

ACTION ITEM 1

That the Board of Pharmacy consider the requests to delay implementation of the electronic pedigree until January 1, 2008.

Discussion
In 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

Over the last year, the Enforcement Committee has been monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. At the February board meeting, the board agreed to form a workgroup on E-Pedigree, which held its first meeting on March 16, 2006 and was attended by over 60 stakeholders.

Of most concern to the many that attended the first workgroup meeting was the implementation date of January 1, 2007. Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

It was expressed that twelve states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as

California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

It was noted that the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Whereas it is possible for board inspectors and staff to identify and verify an e-pedigree, they are not experts in contract law and able to reliably analyze contractual relationships between manufacturers, wholesalers, and pharmacies, such as would be necessary to verify claimed exemptions from e-pedigree requirements based on "normal distribution channel" or "authorized distributor" relationships. Moreover, where status as a "normal distribution channel" or "authorized distributor" depends on private-party designations as such, the board lacks the ability to effectively monitor such designations. These relationships can change without notice, and often out of the view of the board. And furthermore, adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is contrary to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The risk is too great. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

The Enforcement Committee acknowledged the tremendous amount work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1, 2007, the committee asked the stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. To consider the requests for delay in implementation at the April board meeting, the committee requested that the stakeholders submit with their extension requests implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed concern that they could not meet the 2007 date because they are dependent upon the actions of others in the distribution chain.

Based on concern by the industry that they will be unable to meet the January 1, 2007 implementation date for the pedigree requirement, the Senate Business, Professions and Economic Development Committee introduced SB 1476 to extend the implementation date to January 1, 2008. At the April meeting, the board did not take formal action to extend the implementation date to January 1, 2008. However, the board did take a support position on SB 1476. They took this position "reluctantly." This bill also extends the board's sunset provision to January 1, 2010.

At the June Enforcement Committee meeting, Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, Office of the Commissioner and William McConagha, Esquire, Associate General Counsel, Office of the General Counsel presented via telephone recent actions by the FDA regarding the implementation of the regulations related to the Prescription Drug Marketing Act of 1987 (PDMA).

Dr. Bernstein explained that the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug and Cosmetic Act (Act) to establish the requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase the safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the Act establishes the pedigree requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person engaged in the wholesale distribution of a prescription drug in interstate commerce, which is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for the drug. The PDMA states that an authorized distributor of record is a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define "ongoing relationship."

In 1999, the FDA published the final regulations implementing the PDMA. The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to some of the provisions. The regulations defined "ongoing relationship" to include a written agreement between a manufacturer and wholesaler. The regulation specified the fields of information to be included in the drug pedigree and that this information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of these regulations several times.

In February 2004, the FDA delayed the effective date of these regulatory provisions until December 1, 2006, in part because the stakeholders in the U.S. drug supply chain informed the FDA that the industry would voluntarily implement electronic track and trace technology in 2007. If widely adopted, this technology would create a electronic pedigree that would document the sale of a drug product from the place of manufacture through the U.S. drug supply chain to the final dispenser and if properly implemented would meet the requirements of the PDMA regulation. FDA noted that although progress had been made, the use of electronic pedigree would not be widely adopted by 2007. As a result, in June 2006, the FDA announced that it did not intend to delay the effective date of the regulations beyond December 1, 2006. Therefore, the provisions defining an "ongoing relationship" and setting forth the pedigree requirements will go into effect.

FDA recently issued a Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement effort on those prescription drugs most vulnerable to counterfeiting and diversion. Several of the factors included examples. The examples are included only for illustrative purposes and are not meant to be inclusive of all drugs that meet these factors. FDA stated that it may, under appropriate circumstances, initiate regulatory action, including criminal prosecution, for pedigree violations that involve drugs that do not meet the factors.

Dr. Bernstein stated that the enforcement priorities reflect a phased–in approach to the enforcement of the stayed pedigree provisions. FDA contends that by providing guidance on the types of drugs that are of greatest concern, wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into compliance. The policy guide will expire one year from the issue date of the final document.

Dr. Bernstein explained that the FDA Counterfeit Drug Task Force also recommended that stakeholders continue to expeditiously implement widespread use of e-pedigree across the drug supply chain and that the FDA would provide technical assistance if legislation related to e-pedigree is considered in Congress. It is desired that stakeholders continue moving forward in implementing RFID across the drug chain. It is the Task Force's position that RFID is the most promising technology and recommended that stakeholders should consider a phased–in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step. FDA remains committed to facilitating RFID implementation and working with stakeholders, standards organizations and others to do this. It is desired that the FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results. Importantly RFID tracking could be useful for expeditious deployment and re-deployment of medical countermeasures in times of crisis.

It is the Task Force's recommendation that the pedigree would be to the individual drug product package which would require mass serialization and that the NDC number should continue to be closely associated with the product, and for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy. Ideally there should be one numbering schedule in the drug supply chain. To implement a universal and nationally uniform pedigree would require that the PDMA be amended by Congress.

In concluding her presentation, Dr. Bernstein acknowledged and commended the California Board of Pharmacy in its effort to implement an electronic pedigree for prescription drugs. For a secure supply chain, FDA contends that it is imperative that there be transparency and accountability. The widespread adoption of electronic track and trace holds tremendous promise in securing the U.S. supply chain and the lifting of the stay of the PDMA regulations will provide a more effective enforcement of the law. Further, stakeholders (manufacturers, wholesalers, pharmacies, states and the Federal government) must remain vigilant in their responsibility to deliver safe and effective drugs to patients. **(Attachment A)**

The California Pedigree Working Group (CPWG), which is comprised of five trade associations representing all sectors of the pharmaceutical supply chain submitted its comments to support its request to extend the implementation date of the electronic pedigree. It was noted that more than 70 representatives – from over 22 manufacturers, six distributors, nine trade associations, seven pharmacy chains and providers met twice to develop a unified position regarding the electronic pedigree requirements and focused on ensuring that solutions put in place do not limit or otherwise impede patient access to authentic products.

The members of the CPWG stated that there are substantial issues that make the adoption of any electronic pedigree system impossible by January 1, 2007. They contend that neither the industry nor the technologies are capable of complying with board's goals at this time. They are concerned that the

risk of implementation at this early developmental stage in pedigree technology and processes is institutionalizing an immature remedy that is insufficient to repel counterfeiting and other attacks on the pharmaceutical distribution system. Such immature remedies may lead to supply chain disruption.

The working group explained that an extension of the electronic pedigree implementation date would provide the opportunity to continue to develop effective, interoperable solutions for California that will enhance security throughout the supply chain. It would allow time to develop a compliance model based on reasonable and unified steps and to create a non-disruptive and more effective electronic pedigree system. This time would also allow the industry to more carefully and thoroughly introduce major changes within the supply chain that the statutory mandates require.

The CPWG provided the following reasons to extend the implementation date: (1) no uniform standards in place for a drug pedigree (2) the supply chain lacks alignment in critical areas that it needs to resolve such as technology, processes, data security, resource availability, and agreement on the channels through which products should flow (3) a lack of consistency among states and federal requirements – California's pedigree requirements are unprecedented and unparalleled to other states and the federal requirements.

The CPWG identified realistic, short-term milestones that the industry agreed to continue working on in order to progress toward compliance:

- Develop Standards – The first step is to establish standards for product identification, data sets, ownership, and sharing, and interoperability. It is anticipated that the electronic pedigree messaging standards will be adopted by mid-November. Once adopted, it is anticipated that testing will begin around March 2007.
- Support Technologies – While some guidelines for exchanging product information have been developed for use between manufacturers and distributors, this transaction is not a pedigree document. However, it may contain information to assist in the creation of a pedigree. How the new and existing capabilities can be linked needs to be explored.
- Support Education – The CPWG will work to develop education vehicles for preparing its various members for compliance by sharing best practices.

The CPWG stated that it would continue to pilot approaches to define best practices for implementing and managing electronic pedigree solutions. Once there is interoperable software, the supply chain can begin to pilot and validate these systems for use. As an interim step to assure a safe supply chain, it was recommended that the board adopt the "primary distribution channel regulatory" model. This would be in addition to the use by pharmaceutical companies of a variety of counterfeit-resistant technologies on drug packaging and labeling.

In conclusion, the CPWG stated that is working together to ensure that consumers continue to have confidence in their pharmacies and pharmacists, and the prescription drugs dispensed, while ensuring that have unimpeded access to products they need. The anti-counterfeiting guidance should be considered as standards are developed and adopted, new distribution processes are developed, and various technologies become more mature. It is their request that an extension of the electronic pedigree implementation date will provide the opportunity to develop an effective, interoperable solution for California that will enhance security throughout the supply chain, develop a compliance model based on reasonable and unified steps and to create a non-disruptive and more effective electronic pedigree

system, and introduce major changes within the supply chain that the statutory mandates require. **(Attachment B)**

The California Pharmacists Association and the California Society of Health-Systems Pharmacists provided a letter in support of an electronic pedigree to assure a secure drug supply in the United States and commended the board with its efforts in addressing such an important safety issue. However, they cautioned the board that there are serious hurdles that must be overcome before such a system can be put in place. Therefore, they requested that the implementation date be extended substantially beyond 2007 to allow time to work in concert with the federal government in implementation of the Prescription Drug Marketing Act (PDMA) of 1987.

It is their position that the extension should be coupled with adoption of a single standard, interoperability, sightless reading, ease of use and reasonable cost. The additional time will also allow for resolution of other questions, such as the application of the pedigree requirement to the transfer of drugs not addressed in current law (samples, "recycled" drugs) as well as other issues that periodically surface as the electronic pedigree system is developed. They concluded their letter by advising the Board of Pharmacy that forging ahead with electronic pedigree implementation too quickly will result in substantial, and perhaps disastrous disruptions of the current drug distribution system resulting in unintentional harm or delay of medication to the patient. **(Attachment C)**

ACTION ITEM 2

That the Board of Pharmacy approve the strategic plan for the Enforcement Committee.

Discussion
At the April board meeting, the board updated its strategic plan. However, several key tasks remained to finalize the new plan. To finalize the new plan, the Enforcement Committee reviewed and updated its segment of the strategic plan.

The committee reviewed each of the 12 strategic issues for content and relevancy to the goal of licensing. Then the committee reviewed each objective for relevancy under each strategic issue. As a result, some activities were added. **(Attachment D)**

NO ACTION

Prescription Error Data

Last year, Senator Speier sponsored Senate Concurrent Resolution (SCR) 49, which passed. SCR 49 created a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers.

On May 19th, former Executive Officer Patricia Harris spoke to the panel about the board's quality assurance program and provided a summary of pharmacy laws that are used to prevent prescription errors such as patient consultation, medication profiles, and drug therapy review.

On June 2nd, Ms. Harris gave a second presentation on prescription error complaints and the board's citation and fine program. Ms. Harris provided data from 1999 through June 1, 2006. She gave this same presentation to the committee. She also provided examples of prescription error cases and the amount of fines that were issued as a result. This same information will be published in the board's newsletter. **(Attachment E)**

New Federal Requirements Regarding the Sale of Pseudoephedrine and Ephedrine-Containing Products

In March, Congress passed new requirements for the sale of all (single and multi-ingredient) pseudoephedrine and ephedrine-containing products. The new law (Public Law 109-177) places ephedrine, pseudoephedrine (PSE) and phenylpropanolamine in a new Controlled Substances Act (CSA) category of "scheduled listed chemical products." Drug products containing these ingredients are subject to sales restrictions, storage and record keeping requirements. Some of these requirements, which apply to all sellers of these products, went to effect April 8th, and the other requirements will go into effect by September 30, 2006. The Drug Enforcement Administration (DEA) is currently drafting regulations to implement provisions of the new law. **(Attachment F)**

Enforcement Committee Meeting Summary of June 20, 2006 (Attachment G)

Report on Enforcement Actions (Attachment H)

Final Status Report on Committee Strategic Objectives for 2005/2006 (Attachment I)

ATTACHMENT A

U.S. Food and Drug Administration
Before the California Board of Pharmacy
Enforcement Committee
June 20, 2006

FDA's News re: Pedigrees

- Federal pedigree regulations will be fully implemented.
- Vigilance and leadership by States, Federal govt, manufacturers, wholesalers, pharmacies, consumers, and others is essential.
- Further securing the U.S. drug supply continues to be a priority.

FDA

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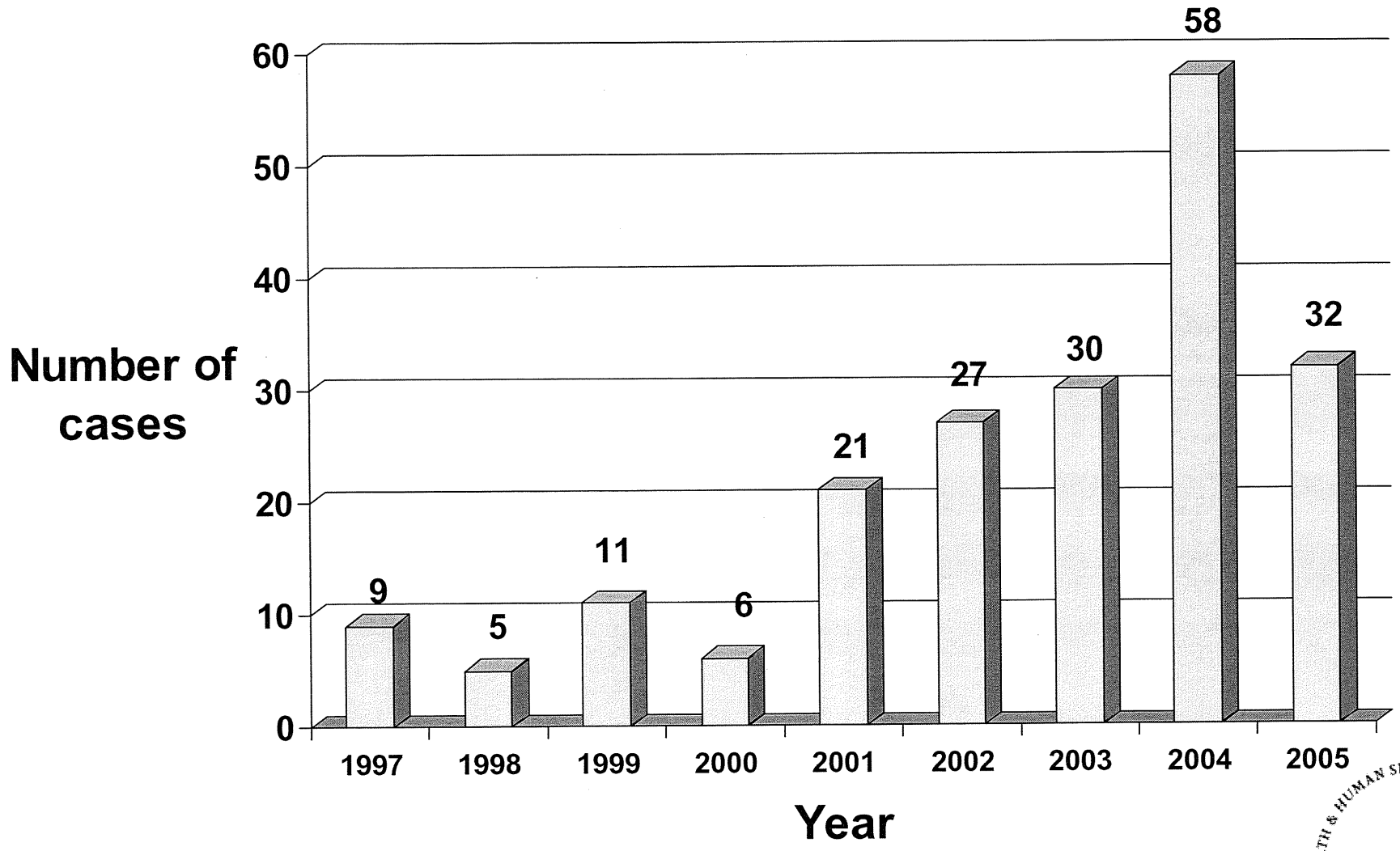
Overview

- Drug Counterfeiting in the U.S.
- Prescription Drug Marketing Act -- Background
- FDA Combating Counterfeit Drugs Initiative – 2006 Report Summary

Counterfeit drug cases opened by FDA per fiscal year



FDA

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PDMA -- Background

- **Pedigree Requirement:**
  - Each person who is engaged in the wholesale distribution of Rx drugs and who is ***not*** the ***manufacturer*** or ***authorized distributor of record***, shall, prior to each wholesale distribution of such drug, provide a statement to the person who receives the drug identifying each prior sale, purchase or trade of such drug.
    - [21 USC 353(e)(2)(A)]

FDA

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PDMA -- Background

- The Federal Food, Drug, and Cosmetic Act defines ***authorized distributor of record*** as a distributor with whom a manufacturer has established an "ongoing relationship."
  - [21 USC 353(e)(3)(A)]

FDA

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PDMA -- Background

- **1999 final rule provisions that were stayed:**
  - **203.3(u):** "Ongoing relationship" defined to include a *written* agreement between manufacturer and wholesaler
  - **203.50:** specifies the information to be included in the drug pedigree; information to be traceable back to 1st sale by manufacturer

FDA

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FDA Counterfeit Drug Task Force Report – June 2006

- **Prescription Drug Marketing Act (PDMA)**
  - Pedigree regulations
- **Electronic track and trace**
  - E-pedigree
  - RFID
  - Technical issues
- **Report and recommendations fully endorsed by the Acting Commissioner**

PDMA Implementation

The Task Force recommends:

- **FDA not continue to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. (Let the stay expire)**
- **FDA issue a draft Compliance Policy Guide (CPG) for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

- Will provide clarity in the drug supply chain regarding who is and is not required to pass a pedigree.
- The CPG will provide factors to consider for where FDA field personnel should target their enforcement efforts and prioritize resources.
- Risk-based focus
  - High value in US market
  - Prior history of counterfeiting or diversion
  - Reasonable probability for new drugs
  - Other violations of law

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Electronic Track and Trace -- E-Pedigree

The Task Force recommends that:

- **Stakeholders work cooperatively to continue to expeditiously implement widespread use of e-pedigree across the drug supply chain.**
- **FDA provide technical assistance if legislation related to e-pedigree is considered in Congress.**

- 2007 goal – will not be met
- FDA will not issue a new forecast or target date for adoption of e-pedigree
- The voluntary approach did not provide industry with enough incentives to meet FDA's deadline.
- Hybrid approaches during a transition period.

FDA

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Electronic Track and Trace --- RFID

The Task Force recommends that:

- **Stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **Stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **FDA remain committed to facilitating RFID implementation and working with stakeholders, standards, organizations, and others.**
- **FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **Stakeholders explore the use of RFID for tracking medical countermeasures.**

- Continue to believe that RFID is the most promising technology
- Not mandating RFID – need a feasible, yet ambitious, timetable
- The CPG for conducting pilot studies for RFID tagging remain in effect as written until December 31, 2007.
- Urge manufacturers to take a risk-based approach
- RFID tracking could be useful for expeditious deployment and re-deployment of medical countermeasures in times of crisis.

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Electronic Track and Trace –Technical Issues

Mass Serialization ---The Task Force recommends that:

- **The NDC Number should continue to be closely associated with the product.**
- **For non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.**

- Mass serialization to identify individual drug product packages is a powerful tool.
- NDC is ubiquitous as a product identifier.
- Ideally, one numbering scheme in the drug supply chain.
- Inappropriate access to NDC # on individual products raises privacy and security issues.

Universal Pedigree/Uniform Pedigree Fields –The Task Force recommends that:

- **FDA provide technical assistance if legislation creating a universal and nationally uniform pedigree is considered in Congress.**

- Universal pedigree– passed by all, for all drugs.
- Uniform – same pedigree information requirements across country.
- To implement universal and nationally, uniform pedigree would require that PDMA be amended by Congress.

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Electronic Track and Trace – Technical Issues

Data Management/Data Security -- The Task Force recommends that:

- **We have no preference whether a distributed versus central database is used, as long as every entity in the chain of custody for the product has access to information about that product all the way back to the manufacturer.**

- It is important that specific event information in the e-pedigree be secure.
- It would be most efficient to let the market and technology dictate how best to capture and access data in e-pedigrees.
- It is essential for FDA and every entity in a drug product's chain of custody to have access to the product's pedigree data.

FDA

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Electronic Track and Trace – Privacy Issues

Labeling/Disclosure/Education

The Task Force recommends that:

- FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains and RFID tag.
- FDA work with private and public sector organizations in their efforts to educate consumers about RFID.

"Turning Off" the RFID Tag

The Task Force finds that:

- We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.

Conclusion

- **Secure supply chain:**
  - Transparency and accountability
- **Widespread adoption of electronic track and trace holds tremendous promise**
- **FDA- more effective enforcement of the law**
- **Stakeholders (manufacturers, wholesalers, pharmacies, States, Federal govt, others) must remain vigilant in their responsibility to deliver safe/effective drugs to the patients**

FDA

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For more information on FDA's Counterfeit Drug Initiative:

www.fda.gov/counterfeit/

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U.S. Food and Drug Administration

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Rockville, Maryland 20852 USA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report – 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.115), as appropriate.

Andrew C. von Eschenbach, M.D.

FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE

I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

II. BACKGROUND

A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;

- If it appeared that the 2007 goal would not be met, we planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

C. 2006 Fact-finding Efforts: Public Workshop, Vendor Display, and Docket

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006.[5] Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

Over 400 people attended the public meeting. Forty-six presentations were made and 27 vendors participated in the vendor display.

Members of the drug supply chain, the technology sector, special interest groups, academia, health professionals, and consumers also filed sixty comments to the public docket that we opened as part of the public workshop.

In addition, we have been attending conferences, meeting with stakeholders, tracking the status of pilot programs, monitoring changes in and use of technologies, participating in standards development, and closely following other influences to remain up-to-date on the relevant issues.

This report is based primarily on information gathered from these fact-finding efforts. It contains our views on outstanding issues related to e-pedigree and RFID implementation, as well as recommendations for additional public and private measures to support our continuing efforts to further secure our nation's drug supply.

III. WHAT IS NEXT FOR PDMA IMPLEMENTATION?

What should FDA do regarding the stay of 21 CFR §§ 203.3(u) and 203.50?

Issue/Background

The PDMA as modified by the Prescription Drug Amendments of 1992 (PDA) amended the Food, Drug, and Cosmetic Act (the Act) to, among other things, establish requirements related to the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the Act requires that

> "...each person who is engaged in the wholesale distribution of a drug***who is not the manufacturer or authorized distributor of record of such drug *** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug. However it does not define "ongoing relationship."

In December 1999, the Agency published final regulations (1999 final rule) (21 CFR part 203) related to the PDMA[6] that were to take effect on December 4, 2000. After publication of the final rule, the Agency received communications from industry, industry trade associations, and members of Congress objecting to the requirements in 21 CFR §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree. Those objecting to the regulations explained that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require authorized distributors to provide pedigree information. Without this information, they explained, secondary wholesalers would not be able to sell the drugs because they would be unable to pass a pedigree that met all the requirements of 203.50. Many secondary wholesalers are small businesses and expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

Based on the concerns raised, the Agency delayed the effective date for those provisions until October 1, 2001[7] in order to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations (the Committee) requested that the Agency review the potential impact on the secondary wholesale pharmaceutical industry and prepare a report to the Committee summarizing the comments and issues raised and the Agency's plans to address these concerns. The Agency's report, which

was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting

and diversion. We do not propose the creation of a list of drugs that meet the criteria, but instead suggest that the CPG provide examples. However, we recommend that FDA not limit its enforcement to just those drugs that meet the factors. Rather, the factors would merely provide guidance for where our field personnel should target their enforcement efforts. The factors to consider for the enforcement focus may include drugs with a high value in the U.S. market, drugs with prior indicators (such as drugs that were involved in diversion cases or counterfeiting), and drugs that are easily counterfeited.

We believe that this CPG would be considered a Level 1 guidance under FDA's good guidance practice (GGP) regulations. (21 CFR §10.115.) Therefore, we recommend that FDA publish a draft version for public comment, evaluate the comments, and then publish a final guidance by December 2006.

We recognize that complying with the stayed regulations may require changes in business practices. Compliance may also require implementation of additional information technology systems to generate a pedigree. Each of these processes may take time to achieve. However, we note that, although the regulations at issue have been stayed since 1999, the fundamental statutory requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain. In addition, we believe that this report and the CPG we advocate herein will focus public attention on this issue such that any wholesalers who thought that they were not subject to the pedigree requirement will have adequate time to take appropriate steps to comply with the regulations.

Furthermore, many States have moved forward with their own pedigree requirements, which often contain requirements in addition to those in the PDMA. We are aware that stakeholders are preparing to meet these State requirements, both electronic (to meet California law) or otherwise. Consequently, they should be that much closer to meeting the federal PDMA requirements as well.

Recommendation:

- **We recommend that FDA not continue to delay the effective date of §§203.3(u) and 203.50 beyond December 1, 2006.**
- **We recommend that FDA issue a draft Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

IV. WHAT IS THE STATUS OF ELECTRONIC TRACK AND TRACE ACROSS THE DRUG SUPPLY CHAIN?

A. What is the progress of the use of e-pedigree in the drug supply chain?

Issue/Background

In the 2004 Task Force Report, we said that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that this would help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. We particularly advocated for the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need.

In our 2006 fact-finding effort, we sought comment on the progress of e-pedigree implementation in the drug supply chain to determine if the goals outlined in the 2004 Task Force Report would be met.

What We Heard

Several comments described completed and ongoing pilot programs for e-pedigree and their successful deployment of e-pedigree in a real-time production environment. Most pilot programs involved distribution with one manufacturer, one wholesaler, and, in some cases, one pharmacy. Many comments stated that e-pedigree can be achieved using either RFID or barcodes. A number of comments stated that standards for e-pedigree are complete and that interoperable software is available. A few comments from manufacturers of already-serialized products said that they have developed track and trace systems capable of providing an e-pedigree through existing internet technologies.

Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. However, many comments suggested that FDA set a specific date by which all products must have an e-pedigree, arguing that without a specific date progress toward adoption will continue to be slow. Some comments recommended that FDA establish realistic phased-in compliance dates for adoption of e-pedigree.

Discussion

In 2004, we were optimistic that widespread implementation of e-pedigree was feasible by 2007 because we were told by many stakeholders in the drug supply chain that this was a realistic goal. Although significant progress has been made to set the stage for widespread use of e-pedigree, unfortunately, this goal most likely will not be met. We will not issue a new forecast or target date for adoption

of e-pedigree because we do not have enough information to do so at this time. Most comments said that it is difficult to predict or designate a target date. We do believe that a timetable with achievable, realistic milestones is crucial to keep e-pedigree implementation on track. Therefore, we recommend that FDA continue to work with members of the drug supply chain to develop such a timetable.

We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps to implement an e-pedigree and States that have championed this cause, such as California. However, it is clear from our recent fact-finding efforts that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's deadline. The mere "risk" of the PDMA regulations being implemented was not enough of an incentive. When PDMA was enacted, the state of technology was not as advanced as it is today, and, as a practical matter the industry could pass only paper pedigrees.

We understand the complexity in moving toward an e-pedigree and recognize that a hybrid approach using both paper and electronic pedigrees will be needed during a transition period. We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration.

If legislation is considered in Congress related to e-pedigrees, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that stakeholders work cooperatively to continue to expeditiously implement widespread use of electronic pedigrees across the drug supply chain.**
- **We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.**

B. What is the progress of the use of RFID on drug product packages?

Issue/Background

We sought comment on the implementation status of RFID, including a description of the obstacles to widespread adoption, an estimate of the timetable, the suggested role of FDA, and the incentives needed to promote adoption.

What We Heard

A majority of the comments agreed that RFID is the most promising technology for track and trace in the drug supply chain. We received many comments describing current obstacles to wider adoption of RFID, including:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;
- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated. A number of comments suggested a phased-in approach for RFID adoption to provide industry sufficient time to explore all options. One comment from a stakeholder closely involved in the development of RFID technology stated that the FDA timeline for RFID adoption is technically feasible, that is, widespread adoption of RFID is feasible by 2007.

Comments noted that progress toward the full adoption of RFID technology is occurring, but that adoption is moving more slowly than previously anticipated. Several pilot projects have been conducted or are underway to test the feasibility of RFID deployment along the prescription drug supply chain, but data is limited.

Most comments said that FDA should not mandate or require the use of RFID in the drug supply chain. Instead, some comments said that FDA should continue to encourage the use of RFID. Many comments said that FDA should actively participate in, support, and facilitate RFID activities, especially those activities of groups working to establish RFID standards and implementation. In addition, many comments said that FDA should take a lead role in developing a public education program about the use of RFID technology on drug products.

Most comments said that incentives would help in the adoption of RFID across the supply chain. Only one comment said that no incentives are needed. Comments suggested the following incentives:

- Financial/tax incentives;

- Mandating mass serialization on drug products, but allowing industry to determine the most appropriate technology to ensure compliance;
- Statutory changes.

Discussion

We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology. We appreciate the candid views and concerns that were shared with us during this fact-finding effort in identifying obstacles to implementation. Within this report, we have tried to address the issues related to those obstacles that are within FDA's purview.

Although we are encouraged by the efforts of GlaxoSmithKline, Pfizer, and PurduePharma in tagging their products, and the efforts of many other companies and wholesalers in exploring and piloting RFID, we are disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, we laid out milestones and goals for RFID implementation based on credible information that stakeholders gave us. Many of these milestones have not been met. The technology vendors uniformly told us that their RFID and e-pedigree solutions and technologies are ready to go, but manufacturers, wholesalers, and retailers are slow to implement them.

We recognize that progress may have been delayed because standards have not yet been established. However, we are encouraged by the progress that industry has made to develop and adopt universal standards. Based on what we heard, those standards are close to completion. Once completed, we would expect to see a rapid growth in the implementation of RFID in the drug supply chain. We look forward to continuing to participate and support this standards development process.

In November 2004, FDA issued a CPG for conducting pilot studies for RFID tagging. In that CPG, FDA excluded biological products as eligible for these pilot studies because we had insufficient information about the impact of radio-frequency (RF) on biologics. To date, we have not received sufficient information to change this policy. Therefore, the CPG continues to remain in effect as written until December 31, 2007. In order to further our understanding of the impact of RF, we have begun our own study to evaluate the potential impact of RFID on drug and biological products. We expect to share the results of this study later this year.

We recognize that implementing an RFID-enabled drug supply chain is challenging. We appreciate the comments advocating a phased-in approach and urge manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of

counterfeiting, and prior history of counterfeiting or diversion, among other things. If a company's products are not "at risk", then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting. Although RFID deployment does have significant start up costs, based on our discussions and what we heard, most stakeholders agree that there are also significant benefits. Not only does the track and trace capability of RFID provide anti-counterfeiting and supply chain security benefits, but it also offers significant savings in the form of better inventory management, reduction in theft and product loss, improved recall efficiency, and reduced paperwork burdens.

RFID also has tremendous potential benefits for drug products used in public health emergencies, such as a pandemic influenza or a bioterrorist attack. RFID tracking could help in expeditious deployment and redeployment of medical countermeasures in times of crisis. FDA should, therefore, encourage manufacturers of these types of products to explore the use of RFID.

We agree with the comments that FDA should not mandate RFID. Although in 2004, we sought voluntary adoption and more widespread use by 2007, we believe that the private sector momentum is moving and that our input on some of the perceived obstacles may jumpstart further adoption interest and momentum. In the 2004 Task Force Report, we laid out a timetable for mass serialization and RFID implementation, as well as steps for businesses and standard-setting issues. Although the timetable goals were not met, we continue to stand by this approach and are prepared to work with stakeholders who wish to take the lead in developing a new, feasible, yet ambitious, timetable.

Recommendation:

- **We recommend that stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.**
- **We recommend that FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **We recommend that stakeholders explore the use of RFID for tracking medical countermeasures.**

V. WHAT TECHNICAL ISSUES RELATED TO ELECTRONIC TRACK AND TRACE NEED RESOLUTION?

1. Mass Serialization

Issue/Background

Mass serialization involves the incorporation of a unique identifier number on each drug package in order to track the individual drug package as it moves through the drug supply chain. We sought comment on mass serialization numbering schemes, including the preferred numbering convention, the merits of incorporating the National Drug Code (NDC) number and its impact on patient privacy, and the timetable for mass serialization across the drug supply chain.

What We Heard

Almost all the comments recommended that industry use a single numbering convention to reduce costs and complexity. One comment noted that multiple numbering schemes could lead to conflicts (e.g., duplicate numbers for the same item) and incompatibility between points in the distribution chain. Several comments suggested that using random numbers for the product identification component of the electronic product code (EPC) could increase security, while concealing proprietary information about the product or manufacturer. However, other comments suggested that the EPC should include the manufacturer ID as part of the code.

Many comments addressed whether or not the NDC should be included in the unique identifier. Many comments were concerned that RFID tags could be surreptitiously read, and if the NDC was included, it could jeopardize the privacy of patients and potentially endanger the drug supply chain. However, pharmacies and their trade groups supported the inclusion of the NDC, arguing that their information systems currently identify products by using the NDC and that they might incur significant costs to change these systems if they used an EPC that did not include the NDC. Some of these comments also noted that the NDC plays an important role in the dispensing process and it would be disruptive to workflow to have to consult another database to link the EPC number to the NDC number. However, a couple of the comments noted that it is not necessary to include the NDC as a component of the unique identifier because, pursuant to FDA regulations (21 CFR §§ 201.2 or 201.25), the NDC is printed on most drug packaging.

Finally, several comments from stakeholders that are closely involved in developing the EPC standards suggested that the numbering convention be sufficiently flexible to accommodate standards-based numbering systems already in use (e.g. NDC for pharmaceuticals, UID for U.S. Department of Defense, EAN.UCC for consumer goods.)

Discussion

We continue to believe that using mass serialization to uniquely identify all drug product packages in the U.S. is a powerful tool in securing the nation's drug

supply. The issues surrounding which numbers should be included in this unique identifier are complex. The NDC number is ubiquitous as an identifier of drug products for inventory, dispensing, and claims adjudication, among other things. However, because it is such a recognized number, an NDC number could compromise patient privacy and supply chain security if it could be read surreptitiously.

We believe that the NDC number is an important product identifier and it should be closely associated with the product. We note that, currently, for most prescription drug product packages, the NDC number is either printed on the packaging or included in a bar code on the package. We do not anticipate this practice to change.

We also recognize that inappropriate access to the NDC number on individual products raises patient privacy and security issues. These competing concerns, however, can be addressed through IT solutions. Therefore, we believe that for drug product packages using RFID or other non-line-of-sight technologies, the unique identifier should either include an encrypted NDC number or provide an accessible link to the NDC number that is readily available to pharmacies to facilitate their needs.

Ideally, there should be one numbering scheme used in the drug supply chain. We recognize that the technology continues to advance and it is difficult to predict what its capabilities will be in the near future.

Recommendation:

- **We recommend that the NDC number should continue to be closely associated with the product.**
- **We recommend that for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.**

2. Universal Pedigree and Uniform Pedigree Fields

Issue/Background

The PDMA limits who is required to pass a pedigree and authorizes FDA to determine what information should be included in the drug pedigree. This information is codified at 21 CFR 203.50. Some States have laws imposing pedigree requirements on members of the drug supply chain not covered under the PDMA. Some States have enacted laws requiring additional information to be included in pedigrees passed with drugs sold in their State. In addition, State requirements differ with respect to the information that must be included in the pedigree. We sought comment on what information pedigrees should contain and how such a uniform standard could be achieved.

What We Heard

Nearly all comments encouraged FDA to implement federal uniform pedigree requirements and standards binding on the drug supply chain and States. Several comments noted the work of stakeholder initiatives, including the Uniform Pedigree Task Force and the EPCglobal e-pedigree standards working group. These stakeholder initiatives suggested data fields that could be captured in a uniform pedigree, including:

- Product Information: drug name, manufacturer, product NDC, dosage form, strength, container size;
- Item Information: lot number and expiration date, quantity of units by lot, product serial number (if serialized);
- Transaction Information: transaction identifier (e.g., PO, invoice) and date, transaction type (e.g., sale, transfer, return), date received;
- Trading Partner Information: business name, address and license of seller, alternate ship-from location of seller, seller contact information for authentication, business name, address and license of recipient, alternate ship-to location of recipient;
- Signatures/Certifications: digital signature of seller, digital signature of recipient.

There was near complete agreement that all wholesalers, not just non-authorized distributors, should be responsible for passing pedigree information. Many of these comments urged FDA to take appropriate steps to require a universal and nationally uniform e-pedigree so that stakeholders do not have to comply with 50 different State pedigree requirements.

Discussion

The PDMA requires a statement/pedigree ("in such form and containing such information as the Secretary may require") to be passed with certain wholesale distributions. The PDMA and FDA's pedigree-related implementing regulations define the information that must be included in a pedigree.

We continue to believe that a universal e-pedigree (i.e., a pedigree passed by all wholesalers, not just those who are not authorized distributors of record) that documents the movement of every prescription drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit drugs from entering the drug supply chain.

We also agree with the comments that a single, national, uniform pedigree would be ideal to help ensure efficient distribution of safe and effective medicines. To be most effective and efficiently communicate chain of custody and other information about the drug product, it would be ideal if all members of the drug

supply chain passed a pedigree that was uniform across all States. Fifty different State pedigrees will no doubt create confusion in the marketplace and could stifle interstate drug trade. For example, the pedigree laws that were enacted in Florida, California, Indiana, and other States contain different requirements.

Under existing law, FDA lacks statutory authority to implement a universal and nationally uniform pedigree. If legislation is considered in this area, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that FDA provide technical assistance if legislation in this area is considered in Congress.**

3. Data Management/Data Security

Issue/Background

For e-pedigree transmission to be successful throughout the drug supply chain, business partners at each point in the supply chain should be able to share information effectively and efficiently. The choice of data management practices and standards becomes an important one for all stakeholders. One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges information with other systems) should be used.

What We Heard

A majority of the comments advocated the use of a distributed database approach to data management. Many noted that a centralized database would be more costly, slower to implement, a threat to patient privacy, and could disrupt drug distribution if the database was unavailable or compromised for some reason. Comments suggested that secure peer-to-peer transactions would be possible under the distributed model. One comment suggested that data management be controlled centrally via a third party, contractually-managed by FDA.

A few comments suggested specific data security measures, such as pedigree documents having digital signatures to maximize document integrity, authentication, and non-repudiation. Some comments referred to existing data transmission standards used elsewhere, specifically Public Key Infrastructure, Federal Information Processing Standards, and the ISO/ICE standards 17799 or 12207. One comment noted that e-pedigrees could be authenticated electronically, using electronic verification of the digital signature and the signed transaction content for each transaction. One comment promoted the use of biometric log-on methods to improve security.

Discussion

It is vital that specific event information contained in the electronic pedigree be secure. We have no preference as to whether the data is housed in a central database or in a distributed scheme. Based on what we heard, it is our understanding that e-pedigree is technologically feasible with either model and even in a hybrid environment, where some data is stored in a central database while other data is distributed across company servers. We believe it would be most efficient to let the market and technology dictate how to best capture and access the data in e-pedigrees.

We do believe that it is essential that every entity in a drug product's chain of custody has access to the product's pedigree data all the way back to the manufacturer, in order to verify and authenticate the pedigree. It is also important for FDA to have access to the information in matters of suspect illegal activity.

Recommendation:

- **We have no preference whether a distributed versus central database is used, as long as every entity in the chain of custody for the product has access to information about that product all the way back to the manufacturer.**

4. Privacy Issues

A. Labeling/Disclosure/Education

Issue/Background

There is general concern that an unauthorized person might be able to read the information from an RFID tag on a drug without the possessor of the drug knowing it, possibly disclosing personally identifiable information or the name of the drug. We sought comment on whether privacy concerns are warranted and whether it is possible for an unauthorized person to read the information from an RFID tag on a drug once that drug is in the consumer's possession. If so, what type of information could be accessed? We also sought comment on how to make consumers aware that an RFID tag is on the drug package and the type of consumer education that would be needed as the use of RFID in the drug supply chain becomes more prevalent.

What We Heard

The majority of the comments indicated that privacy safeguards are needed. However, some pharmaceutical organizations said that patient privacy issues are

not a major concern because many of the prescriptions filled at pharmacies are not dispensed in the original bottles from the manufacturer; the prescriptions are instead placed in a consumer-size container, which would not have an RFID tag. Some comments cited concern about persons gaining unauthorized access to information about the type of drug being taken as well as personal identifying information. Several comments said that the RFID tag should not contain information that identifies the drug (e.g., NDC number). Instead, these comments suggested that the tag should contain a random serialized number so that anyone reading the tag would see only a meaningless number.

Many comments referred to the importance of consumer notice and choice and the use of fair information practices. Comments noted that notice of the presence of an RFID tag on a drug package should be clear, conspicuous, and accurate. Several comments indicated that one way to address the issue of consumer notice is to use a symbol on the package. There was uncertainty, however, as to where the symbol should be placed.

Some comments pointed out that many concerns about privacy are due to concerns about database security (i.e., once the data is collected from an RFID tag, how secure is the database where it is stored?).

The majority of comments said that consumer education is needed for the successful adoption of RFID across the drug supply chain. Many comments indicated that consumers should be informed of the benefits of RFID (e.g., how RFID can help secure the drug supply chain), as well as the risks associated with the technology (e.g., potential threat to privacy). According to some comments, consumers should also be educated about the options that are available for deactivating or removing the RFID tag. Most comments said that FDA, as well as experts in academia, industry, and patient and consumer groups, should be involved in developing education programs.

Discussion

Privacy issues are a real concern for consumers and FDA. These concerns will continue unless there is appropriate disclosure of the presence of an RFID tag on containers given to patients and sufficient education about the application, true risks, benefits, and vulnerabilities associated with RFID tags on drug products. This is no easy task.

Although we support the use of a statement or symbol to disclose the presence of an RFID tag on a drug product package, it is important that manufacturers work with FDA to develop an appropriate message or symbol. Most statements made on the labeling of prescription drug products are regulated by FDA and subject to agency pre-approval. We, therefore, recommend that manufacturers should work with FDA before choosing a statement or symbol to add to their product labeling.

We also are willing to work with stakeholders to develop a uniform statement or symbol that can be used to signal the presence of an RFID tag on a drug product package to use in educational campaigns. Such campaigns would help consumers to readily identify and understand the meaning of the statement or symbol.

We do not propose to issue guidance at this time regarding statements or symbols on drug product labeling to indicate the presence of an RFID tag.

Consumer education is necessary. Potential messages could include educating consumers about RFID, the benefits of its use for patient safety, the privacy risks, possible risks from RF emission, and deactivation and removal of the tag. We do not currently have the resources to lead educational efforts. However, we will work with manufacturers and other stakeholders in their efforts.

Recommendation:

- **We recommend that FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains an RFID tag.**
- **We recommend that FDA work with private and public sector organizations in their efforts to educate consumers about RFID.**

B. "Turning Off" the RFID Tag

Issue/Background

Some people have suggested that the RFID tag should be "turned off" or deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is "turned off". We sought comment on the advantages, disadvantages, and feasibility of deactivating the tag.

What We Heard

Many comments indicated that deactivating or removing the RFID tag at the point of purchase (i.e., the pharmacy) would effectively address privacy concerns. However, some comments pointed out that while deactivating or removing the tag would address privacy concerns, it may also prevent post-sale benefits (e.g., recalls) which would have been possible had the tag remained active/in place.

Some pharmacy groups said that the tag should be deactivated prior to arrival at the pharmacy retailer to ensure that no patient is inadvertently sent home with an active tag. One comment said that in practice, deactivating the tag at the point of sale is not feasible because it would place too much responsibility on pharmacists and may re-expose the drug to unknown radio-frequency effects.

Some comments indicated that FDA should provide guidelines to ensure privacy protections through RFID tag deactivation or removal.

Many comments suggested various deactivation methods. Some of the suggested options were: kill function (total or partial), blocker chips, encryption, read protection, decommissioning with individual tag password, tag destruction, placing RFID tagged objects in a foil lined bag (which would prevent unwanted reads), and database controls. There was no consensus on the best deactivation method. However, a standards organization commented that it is evaluating tag deactivation, taking into consideration the consumer and industry benefits of post-sale uses of RFID tags. The point in the supply chain where RFID tags should/could be deactivated is also being evaluated.

Discussion

There are benefits to both keeping the RFID tag active after sale and deactivating it before dispensing the product. We believe that an active tag can provide valuable information if the drug product finds its way back into the drug supply chain. FDA has found counterfeit and diverted drugs in the drug distribution system when drug wholesalers, third-party return entities, or manufacturers return drugs for credit and/or destruction. Those products with active tags would be easier to identify and track through the supply chain. That said, we respect the privacy concerns, however, and do not believe that it is necessary for an active tag to go to the patient.

It is unclear whether technological methods to deactivate the tag in the normal course of business are mature enough for use in the marketplace at this time. We believe that this issue warrants further discussion among stakeholders, technology experts, and consumers, about the viable options and we are not prepared to make a recommendation at this time.

Recommendation:

- **We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.**

V. CONCLUSION

FDA's vision of a safe and secure drug supply chain is premised on transparency and accountability by all persons who handle the prescription drug, starting with the manufacturer and ending with the pharmacist who hands the drug over to the patient. Drug supply chain efforts that capitalize on advances in electronic track and trace technology to create a secure electronic pedigree further this vision.

With the implementation of the PDMA regulations in December 2006, we expect that supply chain stakeholders will move quickly to adopt electronic track and

trace technology, implementing RFID in a phased-in approach. We recognize that there are important issues that still need resolution, such as privacy concerns and uniform and universal pedigrees that might benefit from further discussion by stakeholders or Congress. However, these issues should not hinder the forward progress and momentum toward widespread adoption that we have witnessed and expect to continue. Companies should continue to tag drug products, build infrastructure across the supply chain for using an e-pedigree, and remain vigilant in their responsibility to provide a safe and effective drug product to the patient.

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[1] The Task Force consists of senior staff from the Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

[2] The FDA Counterfeit Drug Task Force recommendations are detailed in its report, entitled, "*Combating Counterfeit Drugs – A Report of the Food and Drug Administration*," February 18, 2004 (2004 Counterfeit Drug Report) (http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

[3] PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments (PDA) (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 353, and 381) to, among other things, establish requirements related to the wholesale distribution of prescription drug products.

[4] *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*, May 18, 2005 (http://www.fda.gov/oc/initiatives/counterfeit/update2005.html).

[5] The workshop agenda, speakers' presentations, and meeting transcript are available at www.fda.gov/rfidmeeting.html .

[6] 64 FR 67720.

[7] 65 FR 25639.

[8] See http://www.fda.gov/oc/pdma/report2001/

[9] 69 FR 8105.

[10] In this report, the term "comments" includes comments that we heard at the public meeting and written comments submitted to the docket.

FDA News

FOR IMMEDIATE RELEASE
P06-78
June 9, 2006

Media Inquiries:
301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Announces New Measures to Protect Americans from Counterfeit Drugs

The U.S. Food and Drug Administration (FDA) today announced new steps to strengthen existing protections against the growing problem of counterfeit drugs. The measures, which were recommended in a report released today by the agency's Counterfeit Drug Task Force, emphasize certain regulatory actions and the use of new technologies for safeguarding the integrity of the U.S. drug supply.

"The adoption of the FDA Counterfeit Drug Task Force's recommendations will further reduce the risk that counterfeit products will enter the U.S. drug distribution system and reach patients," said Dr. Andrew C. von Eschenbach, the FDA's Acting Commissioner. "We must remain vigilant in our efforts to ensure our nation's drug supply is protected against an increasingly sophisticated criminal element engaging in a dangerous type of commerce."

Among other new measures, FDA will fully implement regulations related to the Prescription Drug Marketing Act of 1987, which requires drug distributors to provide documentation of the chain of custody of drug products -- the so-called "pedigree" -- throughout the distribution system. FDA had placed on hold certain regulatory provisions because of concerns raised at the time about the impact on small wholesalers. Most recently, in early 2004, FDA delayed the effective date of certain regulatory provisions regarding pedigrees to allow the industry time to adopt electronic technology for tracking drugs through the supply chain. Based on information from drug supply stakeholders, the FDA had expected this technology to be in widespread use in the drug supply chain by 2007, but it now appears that these expectations will not be met. Further, FDA has not heard that the concerns raised in the past regarding the impact on small wholesalers remains, and in fact, FDA was encouraged by most drug stakeholders to allow the hold to expire. Doing so would also provide clarity in the drug supply chain regarding who is and is not required to pass a pedigree. Continuing the hold would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices. FDA has, therefore, determined that it can no longer justify not implementing these regulations.

Accordingly, the hold, which will expire in December, will not be continued.

A potential new measure to safeguard the drug supply is the use of electronic track and trace technology, such as radio-frequency identification (RFID), which creates an electronic pedigree (e-pedigree) for tracking the movement of the drug through the supply chain. The FDA had expected this technology to be in widespread use in the drug supply chain by 2007. In early 2004 FDA delayed the effective date of the regulatory provisions regarding pedigrees to allow the industry time to adopt this technology. However, it now appears that FDA's expectations for adoption of the technology by 2007 will not be met. FDA therefore has determined it can no longer justify delaying implementation of the pedigree regulations.

Consistent with recommendations of the Task Force, FDA also announces that, during the next year,

its enforcement of the pedigree regulations will focus on products most susceptible to counterfeiting and diversion. FDA intends to announce in the *Federal Register* the availability of a draft compliance policy guide for public comment describing this enforcement approach. By providing guidance on the types of drugs that are currently of greatest concern to FDA, the agency intends to give wholesale distributors a better idea on where and how to focus their initial energies to come into complete compliance with the regulations (21 CFR Part 203) for all the prescription drugs they distribute. The draft guidance clarifies how FDA intends to prioritize its pedigree-related enforcement resources in 2007. FDA may, under appropriate circumstances initiate regulatory action, including criminal prosecution, for pedigree violations that do not meet the factors listed in the guidance.

The Task Force report also underlines the agency's belief that widespread use of e-pedigrees using electronic track and trace technology, including RFID, would provide an electronic safety net for our nation's drug supply. The report therefore recommends that stakeholders continue to work expeditiously toward that goal, and that their implementation of RFID technology be used first on products most susceptible to counterfeiting and diversion.

Additional subjects discussed in the Task Force's report include the following key issues related to electronic track-and-trace that are in need of resolution:

- Technical aspects of the mass serialization of marketed drugs by assigning a unique identifier or serial number to each drug package as the initial step in development of track and trace technology.
- Importance of a nationwide universal drug pedigree with uniform information in preference to state laws imposing different pedigree requirements.
- Protection of consumer privacy to prevent unauthorized disclosure of information stored in RFID tags when RFID-tagged drug products are dispensed to consumers.
- Consumer education about RFID and the labeling of RFID-tagged drug products, to disclose to consumers when they are receiving RFID-tagged products and to inform consumers of the benefits of RFID technology and how consumers' privacy is being protected.

The new FDA report is largely based on the Task Force's recent findings in numerous contacts with stakeholders, including a February, 2006 public workshop, request for public comment and monitoring of the latest technological developments.

Today's Task Force report is the third in a series of documents exploring the means of ensuring the safety of the U.S. drug supply. The first report, issued in 2004, outlined the framework for protecting the public from counterfeit medicines, and the second report, released last year, assessed the progress toward implementing the 2004 recommendations. All Task Force Reports are posted on FDA's Web at www.fda.gov/counterfeit .

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DRAFT COMPLIANCE POLICY GUIDE 160.900

Prescription Drug Marketing Act – Pedigree Requirements under 21 CFR Part 203

June 2006

Purpose

To clarify for FDA personnel and the regulated industry how the agency intends to prioritize its enforcement efforts during the next year regarding the pedigree requirements in 21 U.S.C. 353(e)(1)(A) and 21 CFR Part 203.

FDA's guidance documents, including this CPG, do not establish legally enforceable rights or responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

Background

The PDMA -- Overview

The Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the Act) to establish requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

The Pedigree Requirements

Section 503(e)(1)(A) of the Act establishes the pedigree requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define "ongoing relationship."

The 1999 Final Rule

In 1999, FDA published final regulations implementing the PDMA (21 CFR Part 203). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in §§ 203.3(u) and 203.50. Section 203.3(u) defines "ongoing relationship" to include a written agreement between manufacturer and wholesaler. Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information in the pedigree should be traceable back to the first sale by the manufacturer.

Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3

(u) and 203.50 several times.

The Electronic Pedigree

In February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree that would document the sale of a drug product from the place of manufacture through the U.S. drug supply chain to the final dispenser. (If properly implemented, an electronic pedigree could thus meet the statutory requirement in section 503(e)(1)(A) of the Act [see above]). Although progress has been made, it appears that the use of electronic pedigree will not be widely adopted by 2007. As a result, in June 2006, FDA announced that it did not intend to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006. (See **insert FR cite when published.**) As such, the provisions defining an "ongoing relationship" and setting forth certain pedigree requirements are in effect thereafter.

The Scope of this CPG

The goal of this CPG is to clarify how we intend to prioritize our pedigree-related enforcement resources during the next year. To that end, the CPG lists factors (below) to guide FDA's enforcement efforts. These are risk-based factors that focus our resources on those drug products that are most vulnerable to counterfeiting and diversion or that are otherwise involved in illegal activity.

Several of the factors include examples. These examples are included only for illustrative purposes and are not meant to be inclusive of all drugs that meet these factors. FDA may, under appropriate circumstances, initiate regulatory action, including criminal prosecution, for pedigree violations that involve drugs that do not meet the factors set forth below.

The enforcement priorities described below reflect a phased-in type approach to the enforcement of the stayed pedigree provisions. By providing guidance on the types of drugs that are currently of greatest concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into complete compliance with 21 CFR Part 203 for all the prescription drugs they distribute. Accordingly, this CPG expires (*insert one year from issue date in final form*).

Factors to Consider for Enforcement Focus

Consistent with our risk-based approach to the regulation of pharmaceuticals, during the next year, FDA intends to give higher priority to enforcement efforts regarding the pedigree requirements in 21 U.S.C. § 353(e)(1)(A) and 21 CFR Part 203 for prescription drugs that fall in the following categories:

FACTOR 1: High Value in the U.S. Market

FDA experience demonstrates that drug products with a high market value or that are high-priced or have high sales volume are more frequently subject to counterfeiting and diversion. Questions to consider for this factor include:

- *Does the drug product have a high sales volume or price in the U.S.?*
    - There are several resources available that rank sales volume and sales in the U.S., including *Drug Topics*. In the context of counterfeiting and diversion, brand name drugs are more likely to fall within this category. Examples of drug products in the U.S. that have a high sales volume and/or price in 2005 include:
        - Lipitor, Nexium, Risperdal, Plavix

- *Is the drug product a "high priced/specialty" product used for a serious or life-threatening disease?*
    - Drugs that are used to treat patients with HIV/AIDS or cancer or other serious or life-

threatening diseases are often higher priced drugs that may be more susceptible to counterfeiting or diversion. Counterfeit versions of these drugs, or those that are illicitly obtained through drug diversion and stored or handled improperly, could result in particularly serious adverse consequences for these patients by depriving them of effective treatments for serious or life-threatening diseases. Examples of these products include:

- Procrit, Epovir, Combivir, immune globulin (IGIV), Gamimune, Gammagard, Epogen, Serostim

- *Is the drug in high demand?*
  - Drugs that are in high demand are vulnerable to counterfeiting and diversion because buyers may be desperate to stock the product, and criminals capitalize on the situation. For example, a drug such as Tamiflu is in high demand due to fears of a possible influenza pandemic. Another example of a drug that is in high demand includes:
    - Oxycontin

- *Is there a shortage of the drug?*
  - A drug may be in high demand if there is a shortage. This could occur if there are manufacturing concerns that limit the ability to manufacture the product. FDA maintains a list of drugs that are currently in short supply at http://www.fda.gov/cder/drug/shortages/default.htm . Current examples of drugs in short supply include:
    - Certain metered dose inhalers, reserpine tablets

FACTOR 2: Prior Indicators

- *Are there prior cases of the drug being counterfeited or diverted in the U.S.? Is there a history of false pedigrees associated with the product?*
  - FDA frequently sees the same drugs as targets for counterfeiting and diversion. In most of these instances, pedigrees are falsified or no pedigrees are provided in order to cover up the true illicit source of the drugs. Based on FDA experience, some examples of drugs that have been counterfeited or diverted are listed below. A longer list is available at [*insert website URL when CPG is issued in final form*]. We note that this list is based on publicly available information and does not include all drugs that have a prior confirmed case of being counterfeited or diverted. Furthermore, inclusion on this list is not meant to imply that the drug is currently counterfeited or diverted or that its safety has been compromised.
    - Viagra, Procrit, Zyprexa, Serostim, Tamiflu, Combivir, Epovir, Sustiva, Trizivir, Zerit, Diflucan, Lamisil

FACTOR 3: Reasonable Probability (for newly-approved drugs)

- This factor is intended to identify those drugs that may not fall within the other factors because there is insufficient marketing history (i.e., this factor "looks forward" for drug products that are new to the market.)
  - *Is there a reasonable probability that the drug may be counterfeited or diverted based on Factors 1 and 2?*
  - *Does the drug have priority review status?*
    - This information is available when a drug is approved and can be found at [*insert website URL when CPG is issued in final form*]
  - *Based on drug products that are in a similar drug class, is the drug predicted to have a high potential market size and value?*

FACTOR 4: Other Violations of Law

The preceding factors notwithstanding, the agency intends to enforce the requirements of 21 U.S.C. § 353(e)(1)(A) and 21 CFR Part 203 (including sections 203.3(u) and 203.50) against wholesale distributors and others who are engaged in conduct related to the manufacture or distribution of

counterfeit drugs, or engaged in the manufacture or distribution of prescription drugs that otherwise violate the Act or other laws. This is true regardless of the type of drug at issue or whether it falls into one of the risk-based factors listed above.

This CPG expires: [insert one year from the issuance of this CPG in final form.]

[Federal Register: June 14, 2006 (Volume 71, Number 114)]
[Rules and Regulations]
[Page 34249-34251]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr14jn06-8]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket Nos. 1992N-0297 (Formerly 92N-0297), 1988N-0258 (Formerly 88N-0258), 2006D-0226]

Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; announcement of effective date; notice of availability; request for comment.

SUMMARY: The Food and Drug Administration (FDA) does not intend to further delay the effective date of certain provisions of the final regulation published in the Federal Register of

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December 3, 1999 (64 FR 67720). The provisions will therefore go into effect on December 1, 2006. In addition, FDA is announcing the availability of a new compliance policy guide (CPG) 160.900 entitled ``Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203'' for public comment. This CPG describes how the agency intends to prioritize its enforcement efforts during the next year with respect to pedigree requirements set forth in the Federal Food, Drug, and Cosmetic Act (the act) and certain FDA regulations.

DATES: The effective date for Sec. Sec. 203.3(u) and 203.50 is December 1, 2006. You may submit written or electronic comments on the CPG by July 14, 2006.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=htt

INFORMATION section for electronic access to the CPG document.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION:

I. Background

A. Implementation of Sec. Sec. 203.3(u) and 203.50 of 21 CFR Part 203

The Prescription Drug Marketing Act of 1987 (the PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the act (21 U.S.C. 331, 333, 353, 381) to establish, among other things, requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the act establishes the so-called ``pedigree'' requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the dates of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a wholesaler that has an ``ongoing relationship'' with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define ``ongoing relationship.''

In 1999, FDA published final regulations implementing the PDMA (part 203 (21 CFR part 203)). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in Sec. Sec. 203.3(u) and 203.50. Section 203.3(u) defines ``ongoing relationship'' to include a written agreement between manufacturer and wholesaler. Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of Sec. Sec. 203.3(u) and 203.50 several times.

Most recently, in February 2004, FDA delayed the effective date of Sec. Sec. 203.3(u) and 203.50 until December 1, 2006, in part because we were informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree documenting the sale of a drug product from its place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, an electronic record could thus meet the pedigree requirements in section 503(e)(1)(A) of the act. Based on a recent fact-finding effort by FDA to assess the use of e-pedigree across the supply chain, however, it appears that industry will not fully implement track and trace technology by 2007.

Today, the agency is announcing that it does not intend to delay the effective date of Sec. Sec. 203.3(u) and 203.50 beyond December 1, 2006. As such, these provisions defining ``ongoing relationship'' and setting forth requirements regarding the information that must appear in pedigrees will go into effect as of December 1, 2006.

B. CPG

We are issuing a draft CPG that describes how we plan to prioritize our enforcement actions during the next year with respect to these new requirements. To this end, FDA is announcing the availability of a new CPG Section 160.900, entitled ``Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203.'' This CPG, which the agency is publishing in draft for comment, lists factors that FDA field personnel are expected to consider in prioritizing FDA's pedigree-related enforcement efforts during the next year. Consistent with our risk-based approach to the regulation of pharmaceuticals, these factors focus our resources on drug products that are most vulnerable to counterfeiting and diversion or that are otherwise involved in illegal activity.

FDA has not provided in the CPG a list of drug products that have been counterfeited in the past. We solicit comment on the merit of providing such a list.

The priorities described in the CPG reflect a phased-in type approach to the enforcement of the stayed pedigree provisions. The CPG will expire 1 year after the final CPG is issued. By providing guidance on the types of drugs that are currently of greatest concern to FDA, we believe that wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into complete compliance with part 203 for all the prescription drugs they distribute.

FDA is issuing this CPG as a level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

We note that guidance documents are not binding on FDA or industry, and, under appropriate circumstances, the agency may initiate regulatory action, including a criminal prosecution, for pedigree violations that do not meet the factors set forth in the CPG.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the CPG document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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III. Electronic Access

An electronic version of this guidance is available on the Internet at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=htt

Dated: June 7, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. 06-5362 Filed 6-9-06; 9:35 am]

BILLING CODE 4160-01-S

ATTACHMENT B

June 16, 2006

Ms. Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, California 95834

Dear Ms. Harris:

The California Pedigree Working Group—comprising five trade associations representing all sectors of the pharmaceutical supply chain—submits to the California State Board of Pharmacy ("Board") the following comments regarding electronic pedigree and California's January 1, 2007 deadline for implementation. This letter seeks to address the Board's request of March 2006 for more information about industry readiness and plans for implementation, and to urge the Board to **extend the implementation date for electronic pedigree requirements in accordance with its authority under California law.**

The California Pedigree Working Group and our member organizations take seriously all threats to our nation's pharmaceutical supply chain. Prescription drug counterfeiting, criminal product tampering, adulteration, diversion, and mislabeling can have obvious adverse outcomes on our products and the patients whose health and lives depend on them. Our members are working together in many ways to ensure that consumers continue to have confidence in their pharmacies and pharmacists, and the prescription drugs dispensed, while ensuring they have unimpeded access to products they need.

The supply chain partners are working diligently to implement new approaches and tools that will provide greater certainty to patients and healthcare providers that the drugs prescribed are authentic. Over the last three years, many of our members have made progress independently to enhance the integrity of the supply chain, including explorations of electronic pedigree solutions. Recent efforts are starting to show promise. Organizations are now gaining the fundamental insights and understanding they need to develop preliminary electronic pedigree systems that can serve all trading partners and consumers, while complying with California law.

Of relevance to the ongoing efforts by the Board is the recent update from the FDA Counterfeit Drug Task Force (June 6, 2006). The Task Force recommended, and the acting FDA Commissioner accepted, that regulations under the Prescription Drug Marketing Act (PDMA) be

implemented this December when the current stay expires. This will institute a drug pedigree requirement at the federal level. Secondly, the report has a candid assessment of progress that has been made toward putting an electronic pedigree system into practice. The FDA acknowledges that there are complexities in moving the technology forward and that full implementation will be challenging.

While our existing system and the efforts of the entire pharmaceutical industry to combat drug counterfeiting have been very successful, we agree that more can be done. We applaud the efforts of the Board of Pharmacy in working toward solutions that further strengthen the security of the drug supply chain in California. In this correspondence we want to address *how* best to achieve this shared overall vision.

Protecting Patients Is the Goal

The primary goal of the Board and the California Pedigree Working Group should be to protect the health and welfare of California patients. The California Pedigree Working Group believes that the Board can best protect the public by continuing to encourage the industry to work together on the various initiatives that are under way, including electronic pedigrees. The Board should resist requiring supply chain members to take premature actions or adopt incomplete systems. To do so could impede progress and shift resources away from effective anti-counterfeiting efforts. We seek solid and strong solutions that will serve the public health.

Under § 4163 of the California Business and Professions Code, the legislature clearly recognized that the task of implementing an industry-wide electronic pedigree system is complex and difficult. The law thus gave the Board the authority to extend the deadline for implementation of its electronic pedigree requirement by one year. We urge the Board to exercise this authority, so we can continue to work toward appropriate solutions.

Current Industry Efforts Are Protecting Patients

Over the past three years, individual manufacturers, distributors, and dispensers have taken significant steps to prevent counterfeits from entering our domestic distribution channels, including:

- The pharmaceutical industry has adopted a counterfeiting reporting practice with the FDA that ensures rapid response to discovery of counterfeits in the supply chain.

- Supply chain members are working closely with law enforcement to aggressively investigate and prosecute counterfeiters, which has resulted in multiple convictions and harsh sentencing.

- Some manufacturers have implemented buy-direct requirements in contracts with their authorized distributors of record to prevent counterfeits from entering the commercial distribution channel from third-party buying. Increasingly, manufacturers are auditing compliance with those agreements.

- Some distributors have adopted policies committing themselves to buy prescription drugs only from the manufacturer or an authorized distributor of record.
- Group purchasing organizations and pharmacy chains have incorporated direct-purchase requirements in their supply contracts with distributors, requiring suppliers to source directly from the manufacturer.
- Many manufacturers have adopted anti-counterfeiting security features, such as color-shifting inks and holograms, on their products to deter counterfeiters from making knockoffs and to enable patients, medical practitioners, the entire distribution chain, and law enforcement to detect fakes.
- The supply chain is working actively to develop reliable track and trace systems that will further ensure the safety and efficiency of the supply of medicines to patients.
- The FDA has reported that the number of new counterfeiting cases dropped dramatically from 2004 to 2005, and the quantities of fakes involved in individual cases appeared to be dropping as well.
- The Pharmaceutical Security Institute (the industry's main anti-counterfeiting investigative organization) indicated in its *2005 Situation Report* that "the new strategies targeting the illegal pharmaceutical trade adopted by the U.S. federal and state authorities over the past years seems to be delivering positive results. . . . The growth of U.S. incidents has slowed down compared to most of the other regions [in the world]."

Barriers to 2007 Implementation

The members of the California Pedigree Working Group agree there are substantial issues that make the adoption of any electronic pedigree system, particularly of the type described by the Board's representatives at a recent Group meeting, impossible by January 1, 2007, in California. Neither the industry nor the technologies are capable of complying with the goals of the Board at this time.

The risk of implementation at this early developmental stage in pedigree technology and processes is institutionalizing an immature remedy that is insufficient to repel counterfeiting and other attacks on the pharmaceutical distribution system. Such immature remedies may lead to supply chain disruptions.

The barriers to complying with the Board's goals are a) the high-speed implementation requirement of b) an immature technology, across c) a highly complex supply chain without d) industry-accepted standards. Section 2 of this letter, "Reasons for Extending the Implementation Date," provides more detail on the barriers to developing a solid and complete electronic pedigree solution, as envisioned by the Board representatives, at the speed necessary for compliance.

No quick, simple solutions can address the significant volume and complexities of the supply chain or the changing landscape of the pharmaceutical industry. Even if the supply chain could

quickly resolve the myriad legal and regulatory/policy issues associated with establishing a state-mandated, electronic pedigree system throughout the supply chain, there are still basic technical issues that need to be addressed. The largely *pilot and experimental* activities of our members represent movement in the right direction, but they are just beginning to help us understand the *scope of the challenges* rather than providing a finished, cohesive solution for the industry and its regulatory bodies.

Further, for an industry-wide electronic pedigree system to be effective, development of *common* standards, technologies, and processes that are acceptable to stakeholders throughout the supply chain must be completed.

Additional Time for a Better Solution

An extension of the electronic pedigree implementation date will provide the opportunity to continue to develop effective, interoperable solutions for California that will enhance security throughout the supply chain. It would allow time to develop a compliance model based on reasonable and unified steps, and to create a non-disruptive and more effective electronic pedigree system. This time would also allow the industry to more carefully and thoroughly introduce the major changes within the supply chain that the statutory mandates require. We believe that anti-counterfeiting guidance should be deployed as standards are developed and adopted, new distribution processes are developed, and various technologies become more mature.

Because supply chain partners are often dependent upon each other's actions to ensure safe, secure, and reliable pharmaceutical delivery, it has been imperative that members of the California Pedigree Working Group: a) fully understand the regulatory requirements and expectations of the Board, and b) determine with the Board how and when these expectations can realistically be met. To that end, on April 25 and again on May 23, 2006, more than 70 representatives—from over 22 manufacturers, six distributors, nine trade associations, seven retail pharmacy chains, and providers—convened to develop a unified position regarding electronic pedigree requirements for the Board's consideration. Above all, the California Pedigree Working Group is focused on ensuring that solutions put in place do not limit or otherwise impede patient access to authentic products.

The remainder of this letter documents:

1. Our understanding of the California Law;
2. Our specific concerns with a January 2007 implementation; and
3. Suggested alternative milestones that we believe would move us closer to our shared goals of a safer and more secure supply chain.

***

1. Our Understanding of the California Law

The prescription drug pedigree requirements under California law are found under the California Business and Professions Code §§ 4034, 4163, 4163.5, and 4163.6. This law mandates that an electronic pedigree must document each transaction that results from the change in ownership and must "move with" or follow the chain of custody.

California Business and Professions Code § 4163 prohibits wholesalers or pharmacies from selling, trading, or transferring prescription drugs without providing a pedigree or from acquiring prescription drugs without receiving a pedigree. California Business and Professions Code § 4034 defines a pedigree as a record containing information regarding each prior transfer of the drug product back to the manufacturer. California Business and Professions Code § 4034 further requires the pedigree to be "in electronic form."

Through written and verbal communications, the Board representatives have made clear that they interpret and intend to enforce these California Business and Professions Code sections such that an individual would be able to identify all previous owners of each discrete, saleable unit of a prescription drug ("item" or "unit") at any point in the prescription drug supply chain, from manufacturer to distributor to pharmacy. The Board representatives also have indicated informally that this may require unique identification of drug products. The Board's communication of requirements, however, is more specific than what is stated in the law, which does not mandate the use of unique item-level identifiers.

2. Reasons for Extending the Implementation Date

The supply chain has moved cautiously in developing an electronic pedigree solution for California due to a number of uncertainties, including technological obstacles, lack of standards, and business process limitations (including information technology). Once technologies to support the creation and movement of an electronic pedigree move beyond the concept and pilot stage and become standardized, widely available, and commercially viable, we believe they could enhance the pedigree process by allowing trading partners to exchange more accurate information than is now possible. But such advanced technologies are not mature. Although there are vendors offering proprietary electronic pedigree applications, our assessment leads us to believe that these would not meet California's goals.

The California Pedigree Working Group has identified several compelling reasons to extend the implementation date. These are summarized as follows:

Uniform Standards Are Not in Place

Currently there is no uniform national or industry standard for what constitutes a drug pedigree. If electronic pedigree tracking is executed, as envisioned by the Board, then a *single standard pedigree or standard data elements* must be agreed upon. In addition, there are no clear standards for the related business processes such as passing pedigrees, authenticating pedigrees, or correcting pedigrees in case of error. Without such agreements, entities within the nation's drug supply system could not effectively and efficiently share the requisite pedigree information.

This problem is especially evident as one considers the complexities of the supply chain where products pass through multiple states that have different pedigree requirements, as well as multiple distribution entities using automated operating and information systems.

Stakeholders in the pharmaceutical supply chain believe that requiring electronic pedigrees before national standards are established is ill advised. Doing so without workable standards and technology could lead to product delays, frequent shortages in some areas, administrative difficulties, and increased distribution costs for manufacturers, distributors, and pharmacies.

In a supply chain where distributors are at the center of a system consisting of hundreds of manufacturers and tens of thousands of different pharmacy settings, without the standards to guide interoperability, multiple competing systems would create technology gridlock:

- **Pharmacies** would have to use any and all systems the manufacturers and distributors decide to use.
- **Distributors** would share in this challenge, as any requirement to deal with multiple solutions operating under different standards would be problematic.
- **Manufacturers, distributors, and pharmacies** may be additionally burdened if other states adopt differing technologies.

The Board of Pharmacy can further the standard-setting process by highlighting the urgency for, and by supporting, standards that address the perspectives and realities of all segments of the drug supply chain.

The Supply Chain Lacks Alignment in Critical Areas

As the stakeholders consider ways to further secure the supply chain through measures such as the adoption of a California electronic pedigree approach, there remain many critical issues to resolve—e.g., technology, processes, data security, resource availability, and agreement on the channels through which products should flow.

While the processes and technologies employed across the supply chain may vary, there is consensus on these important aspects:

a. Technology Interoperability and Reliability Are Critical

Regardless of the technology used to enable electronic pedigree, the system must be *interoperable and reliable across the prescription drug supply chain*, meaning that the system should work no matter how a manufacturer uniquely identifies a drug product, what software a trading partner employs, or what type of infrastructure the downstream drug supply chain partners use. Without interoperability, supply chain partners would be required to invest in and support multiple technological approaches.

While technology alternatives may exist now, many are company-specific, proprietary, and created to address unique business concerns. A full complement of product-appropriate technologies must be deployed and tested for full security of the drug supply and alternative technologies should be considered as long as they are interoperable and reliable. These opportunities are identified in the June 2006 FDA Counterfeit Drug Task Force Report update that discusses the status of electronic track and trace.

b. Consensus Is Needed on Data Communication, Access, and Ownership

Currently there is no industry consensus on the appropriate data communication standard for electronic pedigree. Additionally, existing business practices must be examined to determine how data generated by pedigrees can be shared and accessed by trading partners. An industry data management study has been initiated by the Healthcare Distribution Management Association and the Pharmaceutical Research and Manufacturers of America to *begin* addressing these issues.

c. Process Changes and Their Impacts Must Be Considered

It is currently unclear how various technologies would be integrated in individual companies' business processes to ensure interoperability and consistent execution. Many technical and business process issues are not adequately settled and there are additional uncertainties regarding implementation complexity and the potential for distribution disruptions.

Employee training also will be a critical component of changing current supply chain business processes. Supply chain employees are one of our most valuable assets in combating counterfeiting, and their role in developing a workable system cannot be overstated.

A Lack of Consistency Exists Among State and Federal Requirements

Many states have recently adopted laws and regulations with stringent requirements for licensure of drug distributors and supply chain records. While there appears to be general uniformity in the states' efforts to strengthen wholesale licensing requirements, no two states' pedigree requirements are the same and they often differ from the federal government's pedigree requirements. As members of the supply chain work towards compliance with California law, they must also ensure compliance with other state-specific and federal requirements.

We urge the Board to consider the unique complexity of the California pedigree requirements, and the fact that compliance with other jurisdictions' disparate requirements must be addressed by all members of the pharmaceutical supply chain as they work toward compliance with California's unprecedented and unparalleled requirements.

3. An Alternate Path Toward a Safer, More Secure Supply Chain

To meet the requirements of California's law, supply chain participants must pass an electronic pedigree beginning with receipt from the manufacturer and ending with the dispensing pharmacy or provider. Each change of ownership must be documented in this electronic pedigree. The industry is committed to working with the Board in developing and implementing an appropriate and workable standard to help secure the supply chain.

Over the past several months the California Pedigree Working Group and stakeholders have worked to identify areas of consensus and target those requiring alignment. The industry will continue to work together on these challenges going forward.

Realistic Milestones

While we recognize that compliance is not possible by January 1, 2007, the California Pedigree Working Group has identified realistic, short-term milestones that the industry can agree to continue working on in order to progress toward compliance with the California law.

- **Develop Standards** – The first step in implementing an electronic pedigree system is to establish standards for product identification, data sets, ownership and sharing, and interoperability. There must also be clear national standards for pedigrees and the required data elements.

  To ensure a secure system, we encourage the Board to require that all software vendors offering a solution for the California electronic pedigree requirement certify that their software is *interoperable and reliable.*

  Our members will continue to support the establishment of pedigree standards, although given that the standards process is outside the scope of control of the California Pedigree Working Group, we cannot accurately establish a definitive timeline for standards development and adoption.

- **Support Technologies** – While some guidelines for exchanging product information via the EDI 856 Advance Ship Notice (ASN) transaction have been developed for use between manufacturers and distributors, this transaction is not a pedigree document. However, the ASN does contain information that could *assist* in the creation of a pedigree. Therefore, we will examine how both new and existing capabilities and technologies can be linked.

- **Support Education** – The association members of the California Pedigree Working Group will work to develop education vehicles for preparing their various members for compliance by sharing best practices.

Other Opportunities

The California Pedigree Working Group recognizes that in addition to the significant steps the industry has already taken (as detailed on pages 2-3 of this letter), there are opportunities that could further protect the supply chain in the interim until an electronic pedigree system can be

put in place in California. In an effort to expedite discussions, we have provided some opportunities for consideration:

a. Pilot and Validate All Systems and Technology

The California Pedigree Working Group will continue pilot approaches to define best practices for implementing and managing electronic pedigree solutions. Once we have interoperable software, the supply chain can begin to pilot and validate these systems for use. We would also want to make sure that the software can work in real time so as not to affect productivity in our distribution centers or in our pharmacies. This process, from the time we have interoperable software through the phases of testing, validation, and deployment across all pharmacies in California, will take considerable time.

b. Consider Primary Distribution Channel Regulatory Model as an Interim Step

The primary distribution channel has been defined generally as product moving vertically from a manufacturer, or a manufacturer's agent, to a distributor, or chain pharmacy warehouse or pharmacy, or other licensed dispenser.

Under this concept, pedigrees are not required for prescription drugs that remain within the primary distribution channel. This approach treats each member of the prescription drug supply chain equally, provided they are purchasing and distributing prescription medication within the defined primary distribution channel.

We believe that focusing on requiring a pedigree on products distributed outside of the primary distribution channel is an approach worth considering. Using this approach may provide a practical and immediate interim step.

c. Employ Security Technologies

Pharmaceutical companies currently are using a variety of counterfeit-resistant technologies on drug packaging and labeling to help protect the integrity of the U.S. drug supply. These include overt and covert packaging and labeling features, such as color-shifting inks, holograms, and micro-printing, as well as chemical taggants embedded in the drug product itself. Such technologies provide multiple layers of security that make drug products more difficult for counterfeiters to reproduce accurately. They also are useful for assessing the authenticity of drug products already identified as "questionable."

It is appropriate for companies to have individualized response plans to address incidents of counterfeiting. The unique expertise of each company with its own products must be brought to bear on decisions about the use of anti-counterfeiting technology and the approaches a company takes to responding to counterfeiting of its products.

The California Pedigree Working Group recognizes that there are additional opportunities that could further protect the supply chain in the interim until an effective electronic pedigree system can be put in place. Different segments of the supply chain are assessing a variety of alternative interim measures. The individual members of the California Pedigree Working Group welcome the opportunity to discuss these alternatives with the Board.

***

Conclusion

We support the State of California and the Board in striving toward a safer and more secure supply chain. All our members have the same goal. We appreciate that the Board understands the numerous challenges and the importance of our industry presenting a complete solution as soon as possible.

As the Board assesses the points we have made about the supply chain's complexity and the efforts and risks inherent in an electronic pedigree system, we strongly urge you to also consider that members of our industry have varying levels of resources with which to execute large-scale solutions that are not proven and uniformly accepted. For any mandate to achieve its goals, the solution must utilize nationally recognized and accepted standards that have been tested and proven to function, and shown to be cost-efficient and feasible to implement.

The California Pedigree Working Group requests that the Board extend the implementation date for electronic pedigree. Moreover, we ask that the Board support the industry as it works to develop standards, new distribution processes, and various technologies to enhance the safety and security of the supply chain.

Respectfully submitted,

Patrick Kelly
Vice President, State Government Relations
Biotechnology Industry Organization

Bruce Lott
Vice President of Government Affairs
Generic Pharmaceutical Association

Perry Fri
Senior VP, Industry Relations
Healthcare Distribution Management Association

Kevin N. Nicholson, R.Ph, J.D.
Vice President, Pharmacy Regulatory Affairs
National Association of Chain Drug Stores

Alan Goldhammer
Associate Vice President for Regulatory Affairs
Pharmaceutical Research and Manufacturers of America

About the California Pedigree Working Group

- **Biotechnology Industry Organization** – The Biotechnology Industry Organization (BIO) is the national trade association for the biotechnology industry, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

- **Generic Pharmaceutical Association** – The Generic Pharmaceutical Association (GPhA) represents the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA members manufacture the vast majority of all affordable pharmaceuticals dispensed in the United States. Our products are used in more than one billion prescriptions every year. GPhA's core purpose is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. Toward this end, GPhA advances the interests of our members through initiatives in the scientific, regulatory, and federal/state forums, and in the public affairs arena.

- **Healthcare Distribution Management Association** – For more than 125 years, the Healthcare Distribution Management Association (HDMA) has worked with members to secure a safe, efficient, and reliable healthcare supply chain that is able to provide life-saving health products and services. HDMA members are responsible for ensuring that billions of units of medication are safely delivered to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites in all 50 states in the most efficient manner possible. HDMA members are a vital link in the healthcare system, providing highest quality solutions that remove costs and empower providers to deliver care more effectively. Through our advocacy activities, HDMA operates at the forefront of healthcare, and ensures that members' perspectives and businesses are understood and addressed in legislative and regulatory arenas. For more information on HDMA, please visit www.HealthcareDistribution.org.

- **National Association of Chain Drug Stores** – The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over $700 billion. Other members include almost 1,100 suppliers of products and services to the chain drug industry. NACDS international membership has grown to include 95 members from 29 countries. For more information about NACDS, visit www.nacds.org.

- **Pharmaceutical Research and Manufacturers of America** – The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading

research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industry-wide research and investment reached a record $51.3 billion in 2005.

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HDMA Healthcare Distribution Management Association

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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California Pedigree Working Group
Industry Response Overview

Presentation to
California Board of Pharmacy
Enforcement Committee

June 20, 2006

California Pedigree Working Group - Agenda

- Introductions
- Objectives and outcome of effort
- Process for developing response
- The complexities of the pharmaceutical supply chain
- Industry progress to date
- Summary of response
- Formal request to extend implementation date
- Questions

Trade Association Introductions

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The California Pedigree Working Group has created an industry perspective on pedigree, and a singular response to the Board of Pharmacy

Project Objectives and Outcomes

Objectives

- Provide a response to the request of the California Board of Pharmacy for presentation to the Enforcement Committee Meeting on 6/20/06
- Identify progress to date and what the industry has done over last 2 yrs to tighten supply chain
- Outline current and future steps to advance capabilities and adoption across the supply chain
- Provide industry insight on supply chain complexities and opportunities for the future

Outcome

- Shared point of view on realistic short- and long-term approaches to achieving electronic pedigree compliance
- A collaborative approach with the California Board of Pharmacy

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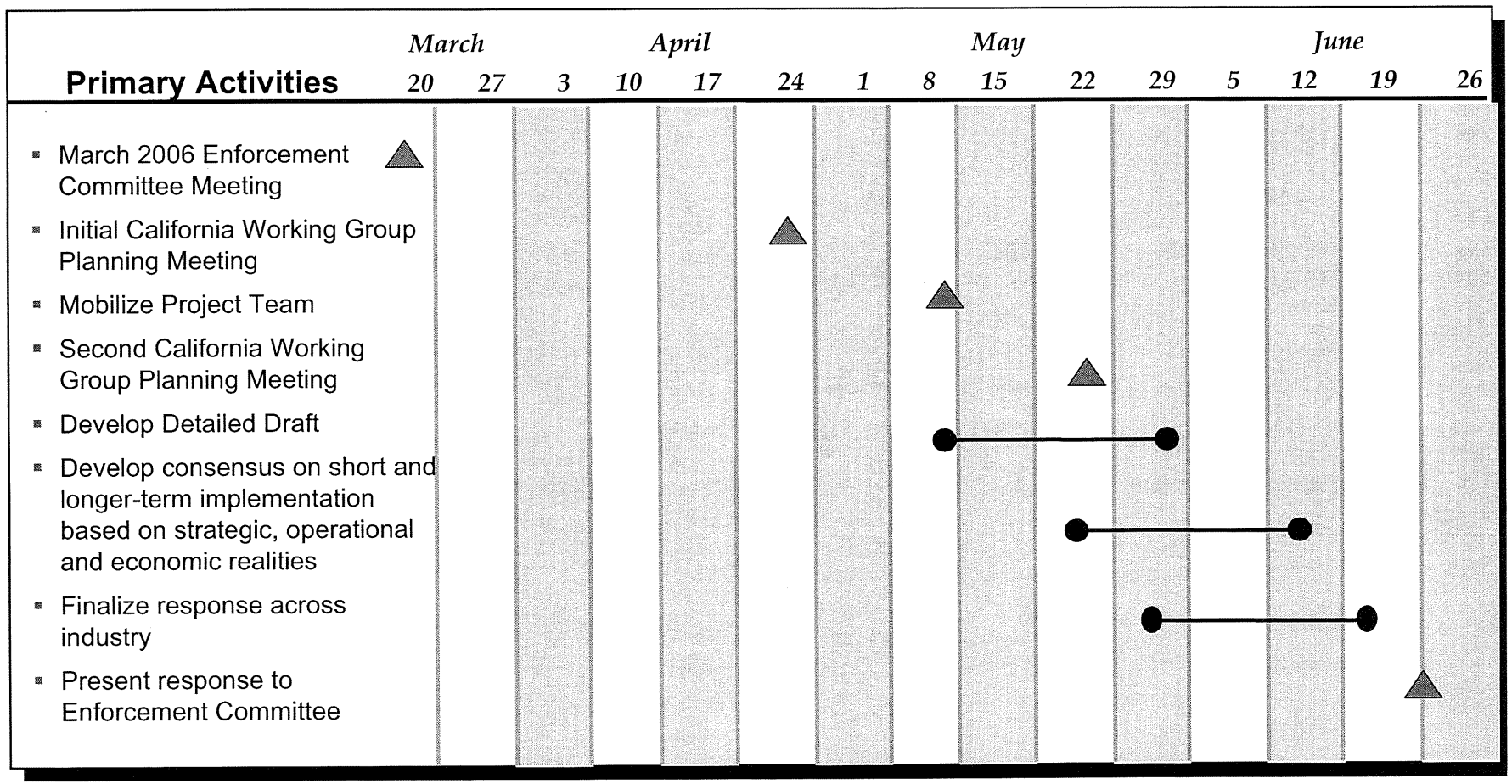
The process for developing an industry consensus on the requirements was a significant undertaking in a short amount of time

California Pedigree Working Group Time Line



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Many of the supply chain trading partners participated heavily and attended one or both of the planning meetings

Manufacturers

- Abbott
- Amgen
- Amylin Pharmaceuticals
- Astrazeneca
- Baxter
- Bayer
- Berlex
- BiogenIdec
- Celgene
- Chiron
- Forest Pharmaceuticals
- Genentech
- GlaxoSmithKiline
- Johnson & Johnson
- Ligand Pharmaceuticals
- Medimmune
- Merck
- Mylan Labs
- Novartis

Manufacturers (continued)

- Pfizer
- Sandoz
- Teva USA
- UCB Pharma
- Wyeth

Trade Associations:

- BIO
- HDMA
- PhRMA
- NACDS
- GPhA
- CPhA – California Pharmacy Association
- FMI California Grocers
- CRA- California Retailers Association
- CHI – California Healthcare Institute

Distributors:

- Amerisource Bergen
- Cardinal Health
- FFF Enterprises
- McKesson
- HD Smith
- PSS World Medical

Community Pharmacies:

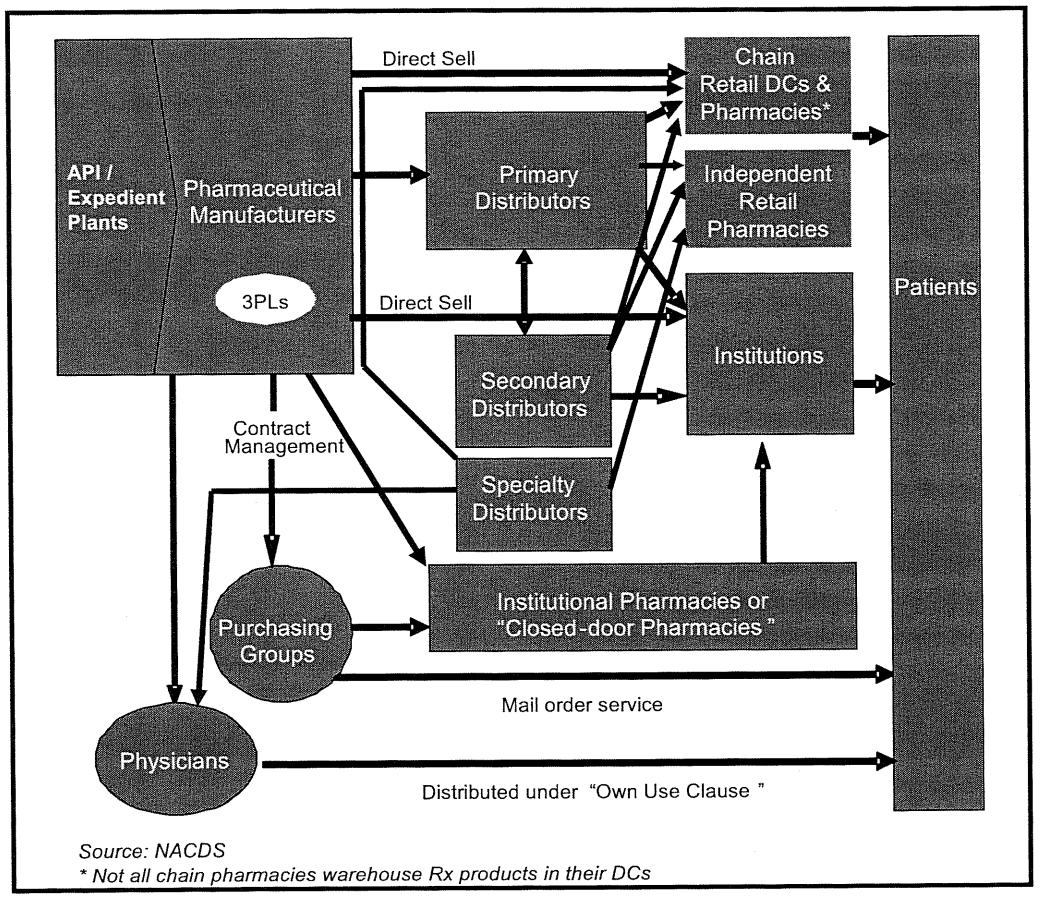
- CVS
- Longs
- Raleys
- Rite-Aid
- Safeway
- Target
- Walgreens
- Wal-Mart

Providers

- Kaiser Permanente

The US Pharmaceutical Supply Chain is a complex web of product and information flows

Supply Chain Dynamics



Source: NACDS

** Not all chain pharmacies warehouse Rx products in their DCs*

California Supply Chain

- In 2005, U.S. pharmaceutical manufacturers sold $20.4B of prescription drugs in California.[1]
- In 2005, there were approximately 287 million prescriptions written by prescribers in California[2]
- There are approximately 4,964 community pharmacies in California, including: approximately 3,122 chain pharmacies and approximately 1,842 independent pharmacies[3]
- There are approximately 13,610 community pharmacists active in the state of California, including 10,826 chain pharmacists with in-state addresses.[4]
- Community pharmacies employ approximately 328,180 full and part-time employees, including[5]:
  - 308,830 chain pharmacy employees
  - 19,350 independent pharmacy employees

Sources:
1) NACDS
2) NACDS
3) HDMA
4) NACDS
5) NACDS

The California Pedigree Working Group has concluded that an extension of the implementation date is required for adequate preparation...

- The challenges are:
  - rapid implementation
  - immature technology
  - complex supply chain
  - lack of industry-accepted standards

- No quick, simple solutions can address the significant volume and complexities of the supply chain or the changing landscape of the pharmaceutical industry

- There are vendors offering proprietary electronic pedigree applications, but our assessment leads us to believe that these would not meet California's goals

- Current solutions do not meet scalability, interoperability and reliability requirements - this process will take considerable time

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...with resolution of specific barriers being priority

- Development of uniform electronic pedigree standards
- Alignment of Supply Chain:
  - Technology reliability and interoperability
  - Data communication, access, and ownership
  - Process changes and impacts
- Consistency between State and Federal requirements

While much progress has been made, we agree more can be done

- Many members have made progress independently to enhance the integrity of the supply chain
- Organizations are now gaining the fundamental insights and understanding they need to develop preliminary electronic pedigree systems that can serve all trading partners and consumers, while complying with California law

Pilots and Research	Standards Setting	Other Developments
A few of the companies who have publicly announced pilots or research toward electronic pedigree (not exclusive or exhaustive): •Pfizer •Purdue Pharma •Wal-Mart •Johnson & Johnson •Ligand Pharmaceuticals •Cardinal Health •FFF Enterprises •McKesson •CVS •Rite-Aid •Safeway •Walgreens	Pedigree Standards process update: • The electronic pedigree specification must first be **ratified** • Once ratification occurs, **test case development and review** is performed (anticipated to take 2-3 months) • Assuming there are no IP issues, **testing** would most likely start in late 1st qtr 2007	• In June 2006, the FDA acknowledged that there are complexities in moving the technology forward • The FDA highlighted that full implementation will be challenging. • FDA has recognized the primary distribution channel as an option, however FDA will require pedigrees for wholesale distributions not conducted by manufacturers or ADRs • Some manufacturers and retailers are requiring implementation of buy-direct requirements in contracts with wholesale distributors • Some manufacturers have adopted anti-counterfeiting security features on their products

The California Pedigree Working Group requests that the Enforcement Committee recommend an extension of the implementation date to allow our progress to continue

- Our members are working together to **ensure that consumers continue to have confidence** in their pharmacies and pharmacists, and the prescription drugs dispensed, while ensuring they have **unimpeded access to products they need**

- We believe that anti-counterfeiting guidance should be considered as **standards are developed and adopted, new distribution processes are developed, and various technologies become more mature**

- An extension of the electronic pedigree implementation date will provide the opportunity to:
  - Develop an **effective, interoperable solution** for California that will enhance security throughout the supply chain
  - Develop a compliance model based on **reasonable and unified steps**, and to create a **non-disruptive and more effective** electronic pedigree system
  - Introduce the **major changes within the supply chain** that the statutory mandates require

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Industry will continue to work towards realistic milestones and identifying other opportunities until a reliable and interoperable electronic pedigree system can be developed

- For an industry-wide electronic pedigree system to be effective, development of common standards, technologies, and processes that are acceptable to stakeholders throughout the supply chain must be completed
- Our members will continue to support the establishment of pedigree standards although, given that the standards process is outside the scope of control of the California Pedigree Working Group, we cannot accurately establish a definitive timeline for standards development and adoption

Realistic milestones:

- Develop standards
- Support technologies
- Support education

Other opportunities:

- Pilot and validate systems and technology
- Consider primary distribution channel regulatory model
- Employ security technologies

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Questions?

ATTACHMENT C

June 19, 2006

Ms. Patricia Harris
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Harris:

In 2004, SB 1307 was passed requiring development and implementation of an electronic pedigree system for any "[sale], trade or transfer of [a] dangerous drug at wholesale . . . ." (B&P Section 4163). The purpose of this requirement was to protect the public from counterfeit drugs and from drugs whose origin and safety could not be ensured. The Pharmacy Board is to be commended for moving California ahead in this important patient safety issue when the Federal Government stayed the Prescription Drug Marketing Act of 1987. However, most recently the FDA Commissioner announced that the regulations will be implemented in December 2006 when the current stay expires. This Act now frees California from having to take the lead to compensate for a lack of Federal Regulation in this area.

There remain serious hurdles, however, to the practical implementation of an electronic pedigree for California and the nation which must be overcome before such a system can be put in place. Therefore, we propose extending the implementation date for California's law substantially beyond 2007 to allow time to work in concert with Federal implementation. The extension should be coupled with adoption of certain requirements for the system to be implemented. The pedigree requirement should not be imposed until the system can meet the minimal requirements of adoption of a single standard, interoperability, sightless reading, ease of use, and reasonable cost. The additional time will also allow for resolution of other questions, such as the application of the pedigree requirement to transfers of drugs not addressed in the current law (samples, "recycled" drugs) as well as other issues that periodically surface as the electronic pedigree system is developed.

While it is very important to secure the safety of the drug supply, the FDA requirements are intended to meet that same goal, specifically aiming at the drugs that are most likely to be counterfeited. While California's requirements may be more extensive than the current FDA regulations we should take the time to implement an electronic pedigree

system in the most effective manner, as the difficulties of implementation will be felt in the entire drug distribution system.

On a whole, forging ahead with electronic pedigree implementation too quickly will result in substantial, and perhaps disastrous disruptions of the current drug distribution system resulting in unintentional harm or delay to the patient. We understand that you have received a letter from the California Pedigree Working Group, which has addressed the complexities of the supply chain. Our two organizations represent the pharmacists who are the final step in evaluating the safety and security of the drug supply. We are the most important link between the drug and the patient. As medication experts we can assist and should be relied upon to help develop the relevant processes. If left unaddressed the resulting problems in access to prescription medication and the associated increases in costs to consumers and private and government health care programs may bring into question any measurable net benefit.

Respectfully,

Lynn W. Rolston
Chief Executive Officer
California Pharmacists Association

Claudia Foutz
EVP and CEO
California Society of Health System Pharmacists

ATTACHMENT D

Goals, Outcomes, Objectives, and Measures

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Objective 1.1:	**Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011:**
Measure:	**Percentage of cases closed or referred within 6 months**
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Objective 1.2:	**Manage enforcement activities for achievement of performance expectations**
Measure:	**Percentage compliance with program requirements**
Tasks:	1. Administer the Pharmacists Recovery Program. 2. Administer the probation monitoring program. 3. Issue citations and fines within 30 days 4. Issue letters of admonition within 30 days 5. Obtain immediate public protection sanctions for egregious violations. 6. Pursue petitions to revoke probation within 90 days for noncompliance with probationary conditions.

Objective 1.3:	**Achieve 100 percent closure on all administrative cases within one year by June 30, 2011.**
Measure:	**Percentage closure of administrative cases within 1 year**

Objective 1.4:	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011.**
Measure:	**Percentage of licensed facilities inspected once every 3 years**
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 2. Inspect sterile compounding pharmacies annually before renewal or before initial licensure. 3. Initiate investigations based upon violations discovered during routine inspections.

Objective 1.5:	**Initiate policy review of 25 emerging enforcement issues by June 30, 2011**
Measure:	**The number of issues**
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.

ATTACHMENT E

Enforcement Committee Meeting
Prescription Errors Presentation
California State Board of Pharmacy

Patricia Harris
Executive Officer
June 20, 2006

Prescription Error Cases

	FY 02/03		FY 03/04		FY 04/05		FY 05/06	
Total Received	329		441		507		337	
Total Closed	228		518		492		397	
Total Substantiated Cases	136	60%	416	80%	367	75%	276	70%
Total Unsubstantiated Cases	92	40%	102	20%	125	25%	121	30%

CLOSED WITH CITATION & FINE

	FY 02/03	FY 03/04	FY 04/05	FY 05/06
Pharmacists	166	185	155	102
Pharmacies	156	176	172	112

PRESCRIPTION ERROR DATA

Medication Error Category	1999 – Nov 2003 Number of Citations	Dec 2003 – Jun 2004 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Jul 2005 – Jun 2006 Number of Citations	Number of Citations / Percent of Total Medication Errors	
Wrong Drug	88	81	55	38	262	42%
Wrong Strength	44	33	43	21	141	23%
Wrong Instructions	21	9	17	11	58	9%
Wrong Patient	12	13	22	17	64	10%
Wrong Medication Quantity	8	7	2	3	20	3%
Other Labeling Error	10	11	7	5	33	5%
Compounding/Preparation Error	7	3	2	3	15	3%
Refill Errors (frequency, timeliness)	5	5	6	3	19	3%
Other (not listed)	10			3	13	2%
Total # Citations for errors (may have more than one category listed)	205	162	154	104	625	100%

PRESCRIPTION ERROR DATA

Citations

Fine Amount	Dec 2003 – Jun 2004 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Jul 2004 – Jun 2005 Number of Citations	Number / Percent of Total Fine Amounts	
$0	16	17	17	50	12%
$100 - $125	16	43	21	80	20%
$250 - $400	81	63	46	190	47%
$500 - $750	39	18	7	64	16%
$1,000	5	2	1	8	2%
$1,500 - $2,000	0	4	3	7	2%
$2,500	2	2	1	5	1%
Total	159	149	96	404	100%

MEDICATION ERROR DATA

1999 – 2003

Common Look-alike / Sound-alike Errors	
Seroquel 200mg	Serzone 200mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg
Prinivil 5mg	Proscar 5mg
Celebrex 200mg	Celexa 20mg
Trazodone 50mg	Tramadol 50mg
Elavil 10mg	Enalapril 10mg

MEDICATION ERROR DATA

July 1, 2004 – June 2006

Common Look-alike / Sound-alike Errors	
Clomiphene	Clonazepam
Dynacin	Dynapen
Marinol	Moban
Metoprolol	Metoclopramide
Videx	Vicodin
Fluextine	Paroxetine
Lanoxin	Levoxyl
Prelone	Pediazole
Prilosec	Prozac

Loxapine	Lexapro
Lisinopril	Lovastatin
Lisinopril	Lipitor
Novolin N	Novolin 70/30
Norvasc	Navane
Proscar	Prinivil
Purinthal	Propylthiouracil
Darvocet	Fioricet
Alprazolam	Atenolol
Imipramine	Imitrex

MEDICATION ERROR DATA

July 1, 2004 – June 2006 Continued

Common Look-alike / Sound-alike Errors	
Clorpromazine	Chlorpropamide
Prednisone	Prednisolone
Topramax	Toprol
Mircette	Micronor
Nasocort	Nasolide
Coreg	Cozaar
Norvasc	Namenda
Zyprexa	Zyprexa Zydisc

Hydralzine	Hydrochlorthiazide
Clonidine	Clonazepam
Glipizide	Glyburide
Furosemide	Fluxetine
Lorazepam	Levoquin
Miralax	Maalox
Paxil	Prozac

Prescription Error Cases

$500 Fine

- **Case 1:** An 84 year old woman was prescribed Namenda 10mg for treating Alzheimer symptoms. The pharmacist incorrectly dispensed Norvasc 10mg (a drug to lower blood pressure), which the patient took for 28 days before the error was discovered. The patient showed symptoms of weakness, confusion, low blood pressure, and declined physically.
- **Case 2:** A premature infant weighing 4.3 pounds with respiratory difficulties was prescribed Aminophyllin 25mg/ml (dilate lungs) with directions to administer 1.6 ml or 4mg every 8 hours. The pharmacist miscalculated the dose and the patient received 40mg (10 times) resulting in re-hospitalization. Patient was weaned off the high dose and recovered.
- **Case 3:** A 16 year old male was prescribed Oxycodone 5mg/5ml and to take 5ml to relieve pain. The pharmacist incorrectly dispensed Oxycodone 20mg/1ml and to take 5ml. The patient went into respiratory failure after one dose and was hospitalized. Investigation showed the prescription written by the prescriber was incomplete and did not indicate strength and dosage to be administered. The pharmacist failed to clarify the order prior to dispensing.

Prescription Error Cases

$1,000 Fine

- **Case 1:** A patient with an insufficient thyroid was prescribed liothyronine 9.25 micrograms (a thyroid replacement drug.) The pharmacist incorrectly dispensed liothyronine 9.25 milligrams (1,000 times the prescribed dose). The patient exhibited symptoms of thyroid toxicity such as psychosis, increased heart rate, memory loss and weakness. The patient was hospitalized and taken off the high dose.
- **Case 2:** An 82 year patient was prescribed Cardura (to treat his prostrate cancer). The pharmacist incorrectly dispensed Coumadin (a blood thinner), which the patient took for 9 days before discovering the error. The patient was admitted to a hospital intensive care unit for a severe bleeding disorder. Patient eventually recovered but was hospitalized for a long period of time.
- **Case 3:** A patient was prescribed Clonazepam 2mg (controlled substance used to treat anxiety). The pharmacist incorrectly dispensed Clonidine 0.2mg (used to treat hypertension), which the patient took for 5 months. The patient experienced low blood pressure and had difficulty concentrating. The patient went to the emergency room and was admitted to the hospital for 2 weeks to wean the patient off the medication. The pharmacist was also cited for failure to provide consultation.

PRESCRIPTION ERROR CASES

$2,500 Fine

- **Case 1:** A patient was scheduled to have a procedure and was prescribed two drugs: Lorazepam 2mg, take 1 tablet ½ hour before procedure and Promethazine 25mg, take 1 tablet ½ hr before procedure (both drugs are used to reduce anxiety). The pharmacist dispensed the two drugs to take five tablets of each ½ hr before the procedure. The patient experienced a toxic effect and expired from a combination of drugs including the overdose and other drugs used during the procedure. The investigation showed the prescriber had written brackets around the 3 drugs with the directions to take ½ hour prior to the procedure in the doctor's office. The prescription was ambiguous and the pharmacist failed to clarify the order prior to dispensing.

- **Case 2:** During a night shift, a patient in a hospital intensive care unit was prescribed an intravenous infusion containing a drug called phenylephrine (used to raise the blood pressure). The pharmacy technician prepared the infusion but incorrectly used a drug called Phentolamine (lowers blood pressure). The pharmacist failed to accurately verify the drug used by the pharmacy technician to prepare the infusion and the patient went into cardiac arrest and expired. The investigation substantiated the hospital pharmacy's system for verifying drug orders prepared by pharmacy technicians was not followed as well as inadequate staffing patterns (hospital administration refused to add staff to the night shift) which contributed to the Sentinel Event. The hospital and the pharmacist were each fined $2,500.

PRESCRIPTION ERROR CASES

$2,500 Fine

- **Case 3:** A cancer patient was prescribed a drug called Cisplatin at a dose of 50mg, which the patient received 4 times previously. For the most recent dose, the pharmacist incorrectly dispensed Cisplatin 500mg (ten times the prescribed dose). The patient experienced significant side effects with lowering of the blood cells and required transfusions; however the patient died. An investigation revealed the pharmacist failed to clarify the prescription, which the dose was unclear and ambiguous as written by the prescriber.

ATTACHMENT F

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Melissa Madigan, Professional Affairs Senior Manager

DATE: June 2, 2006

RE: Drug Enforcement Administration Implementation of the Combat Methamphetamine Epidemic Act of 2005

In response to the National Association of Boards of Pharmacy's (NABP) request for information regarding Drug Enforcement Administration's (DEA) implementation of the Combat Methamphetamine Epidemic Act of 2005, DEA is currently drafting regulations to implement the provisions of the Act, and cannot specifically address questions at this time. However, DEA has invited NABP to comment on these regulations once they are published.

For a copy of the Act and the guidance document "General Information Regarding the Combat Methamphetamine Epidemic Act," which gives information regarding effective dates, sales limits, and other requirements, please consult the DEA Web site at www.deadiversion.usdoj.gov.

cc: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control
NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

Federal Limits on Pseudoephedrine-Containing Products

In March, Congress passed new requirements for the sale of all (single and multi-ingredient) pseudoephedrine and ephedrine-containing products. The new law (Public Law 109-177) places ephedrine, pseudoephedrine (PSE), and phenylpropanolamine in a new Controlled Substances Act (CSA) category of 'scheduled listed chemical products'. Drug products containing ephedrine, PSE, and phenylpropanolamine are subject to sales restrictions, storage requirements and record keeping requirements. Some of these requirements, which apply to all sellers of these products, go into effect by April 8th; others require compliance by September 30, 2006.

Effective April 8, 2006	
	3.6 gram daily sales limit
	9.0 gram 30-day sales limit
	All non-liquid forms must be sold in blister packs (with a few exceptions)
	Mail-service pharmacy must verify patient's identification before shipping product
	Mail-service pharmacy 7.5 gram 30-day sales limit
Effective by September 30, 2006	
	Products must be placed behind a counter or in a locked cabinet
	Seller must maintain a written or electronic logbook** which must identify: • the product name • the quantity sold • names and addresses of purchasers • dates and times of sales
	Purchasers must present a photo ID* and sign the logbook
	Sellers must self-certify to the U.S. Attorney General that their sales personnel have been trained as required by regulations (yet to be promulgated)
	7.5 gram 30-day sales limits for mobile sellers (such as kiosks in airports)
* Logbook and ID requirements do not apply to sales of 60 mg or less of pseudoephedrine.	

There are more changes on the horizon. Many of the requirements that go into effect by September 30th will require promulgation of regulations to address logbook and training requirements and ways to address privacy issues that could arise with the logbook. Additionally, the American Pharmacists Association is working to get confirmation from the DEA that the regulations do not apply to prescribed products, including prescribed over-the-counter products.

ATTACHMENT G

California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Workgroup on E-Pedigree
June 20, 2006

Radisson Hotel Sacramento
500 Leisure Lane
Sacramento, CA 95815

Present: William Powers, Chair and Board President
Stan Goldenberg, R.Ph.and Board Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General
LaVonne Powell, Staff Counsel

Call to Order

Chair William Powers called to the meeting to order at 9:30 a.m.

Presentation of Prescription Error Data

Executive Officer Patricia Harris reported that last year, Senator Speier sponsored Senate Concurrent Resolution (SCR) 49, which passed. SCR 49 created a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers.

On May 19th, she spoke to the panel about the board's quality assurance program and a summary of pharmacy laws that are used to prevent prescription errors such as patient consultation, medication profiles, and drug therapy review.

On June 2nd, she gave a second presentation on prescription error complaints and the board's citation and fine program. Ms. Harris provided data from 1999 through June 1, 2006. She gave this same presentation to the committee. She also provided examples of prescription error cases

and the amount of fines that were issued as a result. This same information will be published in the board's newsletter.

New Federal Requirements Regarding the Sale of Pseudoephedrine and Ephedrine-Containing Products

Supervising Inspector Robert Ratcliff reported that in March, Congress passed new requirements for the sale of all (single and multi-ingredient) pseudoephedrine and ephedrine-containing products. The new law (Public Law 109-177) places ephedrine, pseudoephedrine (PSE) and phenylpropanolamine in a new Controlled Substances Act (CSA) category of "scheduled listed chemical products." Drug products containing these ingredients are subject to sales restrictions, storage and record keeping requirements. Some of these requirements, which apply to all sellers of these products, went to effect April 8th, and the other requirements will go into effect by September 30, 2006. The Drug Enforcement Administration (DEA) is currently drafting regulations to implement provisions of the new law.

Review of Strategic Plan – Enforcement Goal and Strategic Objectives/Activities for 2006-2011

Assistant Executive Officer Virginia Herold reported that at its April meeting, the board updated its strategic plan. However, several key tasks remain to finalize the new plan, which will be reviewed by the board at the July meeting. To finalize the new plan, the Enforcement Committee reviewed and updated its segment of the strategic plan.

The Enforcement Committee reviewed each of the 12 strategic issues for content and relevancy to the enforcement goal and each objective for relevancy under each strategic issue.

The committee recommended that the board approve the committee's strategic plan.

Workgroup on E-Pedigree

Presentation by the Federal Food and Drug Administration (FDA)

Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, Office of the Commissioner and William McConagha, Esquire, Associate General Counsel, Office of the General Counsel presented via telephone recent actions by the FDA regarding the implementation of the regulations related to the Prescription Drug Marketing Act of 1987 (PDMA).

Dr. Bernstein explained that the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug and Cosmetic Act (Act) to establish the requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase the safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

Section 503(e)(1)(A) of the Act establishes the pedigree requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person engaged in the wholesale distribution of a prescription drug in interstate commerce, which is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for the drug. The PDMA states that an authorized distributor of record is a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define "ongoing relationship."

In 1999, the FDA published the final regulations implementing the PDMA. The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to some of the provisions. The regulations defined "ongoing relationship" to include a written agreement between a manufacturer and wholesaler. The regulation specified the fields of information to be included in the drug pedigree and states that this information must be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of these regulations several times.

In February 2004, the FDA delayed the effective date of these regulatory provisions until December 1, 2006, in part because the stakeholders in the U.S. drug supply chain informed the FDA that the industry would voluntarily implement electronic track and trace technology in 2007. If widely adopted, this technology would create a electronic pedigree that would document the sale of a drug product from the place of manufacture through the U.S. drug supply chain to the final dispenser and if properly implemented would meet the requirements of the PDMA regulation. FDA noted that although progress had been made, the use of electronic pedigree would not be widely adopted by 2007. As a result, in June 2006, the FDA announced that it did not intend to delay the effective date of the regulations beyond December 1, 2006. Therefore, the provisions defining an "ongoing relationship" and setting forth the pedigree requirements will go into effect.

FDA has issued a Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement effort on those prescription drugs most vulnerable to counterfeiting and diversion. Several of the factors included examples. The examples are included only for illustrative purposes and are not meant to be inclusive of all drugs that meet these factors. FDA stated that it may, under appropriate circumstances, initiate regulatory action, including criminal prosecution, for pedigree violations that involve drugs that do not meet the factors.

Dr. Bernstein stated that the enforcement priorities reflect a phased–in approach to the enforcement of the stayed pedigree provisions. FDA contends that by providing guidance on the types of drugs that are of greatest concern, wholesale distributors will have a better idea of where and how to focus their initial energies as they implement systems to come into compliance. The policy guide will expire one year from the issue date of the final document.

Consistent with their risk-based approach to regulation of prescription drugs, FDA identified factors that would give a higher priority to enforcement efforts regarding the pedigree

requirements. The risk-based focus for prescription drugs is high value in US market, prior history of counterfeiting or diversion and significant impact on the patient's health, reasonable probability for new drugs, and other violations of law by the wholesale distributor.

Dr. Bernstein explained that the FDA Counterfeit Drug Task Force also recommended that stakeholders continue to expeditiously implement widespread use of e-pedigree across the drug supply chain and that the FDA would provide technical assistance if legislation related to e-pedigree is considered in Congress. It is desired that stakeholders continue moving forward in implementing RFID across the drug chain. It is the Task Force's position that RFID is the most promising technology and recommended that stakeholders should consider a phased–in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step. FDA remains committed to facilitating RFID implementation and working with stakeholders, standards organizations and others to do this. It is desired that the FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results. Importantly RFID tracking could be useful for expeditious deployment and re-deployment of medical countermeasures in times of crisis.

It is the Task Force's recommendation that the pedigree would be to the individual drug product package which would require mass serialization and that the NDC number should continue to be closely associated with the product, and for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy. Ideally there should be one numbering schedule in the drug supply chain. To implement a universal and nationally uniform pedigree would require that the PDMA be amended by Congress.

The Task Force did not have a preference whether a distributed or central database is used to track the pedigree; as long as every entity in the chain of custody for the prescription drug has access to the information about that drug all the way back to the manufacturer. It is important the information be secure and it is more efficient to let the market and technology dictate how best to capture and access the date in electronic pedigrees. However, it is essential for FDA and every entity in a drug product's chain of custody to have access to the product pedigree data.

Further the Task Force recommended that the FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains an RFID tag and to work with the private and public sector to educate consumers about RFID. The Task Force did not have sufficient time to review the issue of "turning off" the RFID tag to assure a patient's privacy.

In conclusion, Dr. Bernstein acknowledged and commended the California Board of Pharmacy in its effort to implement an electronic pedigree for prescription drugs. For a secure supply chain, FDA contends that it is imperative that there be transparency and accountability. The widespread adoption of electronic track and trace holds tremendous promise in securing the U.S. supply chain and the lifting of the stay of the PDMA regulations will provide a more effective enforcement of the law. Further, stakeholders (manufacturers, wholesalers, pharmacies, states and the Federal government) must remain vigilant in their responsibility to deliver safe and effective drugs to patients.

Presentation by the California Pedigree Working Group

The California Pedigree Working Group (CPWG), which is comprised of five trade associations representing all sectors of the pharmaceutical supply chain submitted its comments to support its request to extend the implementation date of the electronic pedigree. It was noted that more than 70 representatives – from over 22 manufacturers, six distributors, nine trade associations, seven pharmacy chains and providers met twice to develop a unified position regarding the electronic pedigree requirements and focused on ensuring that solutions put in place do not limit or otherwise impede patient access to authentic products.

The five trade associations are BIO, which represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. GPhA, which is the Generic Pharmaceutical Association representing manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals and suppliers of other goods and services to the generic pharmaceutical industry. The HDMA, Health Distribution Management Association, represents wholesalers nationwide. The National Association of Chain Drug Stores (NACDS) represents over 35,000 retail chain pharmacies and suppliers, and employing over 108,000 pharmacists. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the pharmaceutical and biotechnology companies.

The CPWG noted that over the past three years, individual manufacturers, distributors, and dispensers have taken significant steps to prevent counterfeits from entering the domestic distribution channels, including: adopting a counterfeit reporting practice with the FDA that ensures rapid response to discovery of counterfeits in the supply chain, working closely with law enforcement to aggressively investigate and prosecute counterfeiters, buy-direct requirements in contracts between manufactures and authorized distributors of record, adopting anti-counterfeiting security features, and working actively to develop reliable track and trace systems.

The members of the CPWG stated that there are substantial issues that make the adoption of any electronic pedigree system impossible by January 1, 2007. They contend that neither the industry nor the technologies are capable of complying with board's goals at this time. They are concerned that the risk of implementation at this early developmental stage in pedigree technology and processes is institutionalizing an immature remedy that is insufficient to repel counterfeiting and other attacks on the pharmaceutical distribution system. Such immature remedies may lead to supply chain disruption.

The working group explained that an extension of the electronic pedigree implementation date would provide the opportunity to continue to develop effective, interoperable solutions for California that will enhance security throughout the supply chain. It would allow time to develop a compliance model based on reasonable and unified steps and to create a non-disruptive and more effective electronic pedigree system. This time would also allow the industry to more carefully and thoroughly introduce major changes within the supply chain that the statutory mandates require.

The CPWG provided the following reasons to extend the implementation date: (1) no uniform standards in place for a drug pedigree (2) the supply chain lacks alignment in critical areas that it needs to resolve such as technology, processes, data security, resource availability, and agreement on the channels through which products should flow (3) a lack of consistency among states and federal requirements – California's pedigree requirements are unprecedented and unparalleled to other states and the federal requirements.

The CPWG identified realistic, short-term milestones that the industry agreed to continue working on in order to progress toward compliance:

- Develop Standards – The first step is to establish standards for product identification, data sets, ownership, and sharing, and interoperability. It is anticipated that the electronic pedigree messaging standards will be adopted by mid-November. Once adopted, it is anticipated that testing will begin around March 2007.
- Support Technologies – While some guidelines for exchanging product information have been developed for use between manufacturers and distributors, this transaction is not a pedigree document. However, it may contain information to assist in the creation of a pedigree. How the new and existing capabilities can be linked needs to be explored.
- Support Education – The CPWG will work to develop education vehicles for preparing its various members for compliance by sharing best practices.

The CPWG stated that it would continue to pilot approaches to define best practices for implementing and managing electronic pedigree solutions. Once there is interoperable software, the supply chain can begin to pilot and validate these systems for use. As an interim step to assure a safe supply chain, it was recommended that the board adopt the "primary distribution channel regulatory" model. This would be in addition to the use by pharmaceutical companies of a variety of counterfeit-resistant technologies on drug packaging and labeling.

In conclusion, the CPWG stated that is working together to ensure that consumers continue to have confidence in their pharmacies and pharmacists, and the prescription drugs dispensed, while ensuring that have unimpeded access to products they need. The anti-counterfeiting guidance should be considered as standards are developed and adopted, new distribution processes are developed, and various technologies become more mature. It is their request that an extension of the electronic pedigree implementation date will provide the opportunity to develop an effective, interoperable solution for California that will enhance security throughout the supply chain, develop a compliance model based on reasonable and unified steps and to create a non-disruptive and more effective electronic pedigree system, and introduce major changes within the supply chain that the statutory mandates require.

Letter from the California Pharmacists Association and California Society of Health-System Pharmacists

These two organizations representing pharmacists provided a letter in support of an electronic pedigree to assure a secure drug supply in the United States and commended the board with its efforts in addressing such an important safety issue. However, they cautioned the board that there are serious hurdles that must be overcome before such a system can be put in place. Therefore, they requested that the implementation date be extended substantially beyond 2007 to allow time

to work in concert with the federal government in implementation of the Prescription Drug Marketing Act (PDMA) of 1987.

It is their position that the extension should be coupled with adoption of a single standard, interoperability, sightless reading, ease of use and reasonable cost. The additional time will also allow for resolution of other questions, such as the application of the pedigree requirement to the transfer of drugs not addressed in current law (samples, "recycled" drugs) as well as other issues that periodically surface as the electronic pedigree system is developed. They concluded their letter by advising the Board of Pharmacy that forging ahead with electronic pedigree implementation too quickly will result in substantial, and perhaps disastrous disruptions of the current drug distribution system resulting in unintentional harm or delay of medication to the patient.

Discussion

The Enforcement Committee discussed the various concerns. They expressed disappointment that the California Pedigree Working Group failed to provide actual milestones for implementation. One milestone provided was the testing of the pedigree messaging standards. EPCglobal reported that it anticipates the adoption of these standards by mid-November 14 and the CPWG proposed to test the standards around March 2007. While repeated concern was raised that technology was not available to implement an electronic pedigree, the committee commented that they have heard from many that the technology is available now for implementation of the requirements in 2007.

The committee again expressed its intent that an electronic pedigree is implemented and that they wanted to see actual milestones that will reflect efforts to reach compliance.

ATTACHMENT H

State of California **Department of Consumer Affairs**

Memorandum

To: **BOARD MEMBERS** **Date: July 19, 2006**

From: **SUSAN CAPPELLO**
Enforcement Coordinator
Board of Pharmacy

Subject: **Enforcement Statistics**

Attached you will find the enforcement statistics for fiscal year 2005/2006 and a three year comparison of enforcement statistics.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Complaints/Investigations					
Initiated	407	254	434	602	1697
Closed	548	408	410	589	1955
Pending (at the end of quarter)	637	587	683	633	633
Cases Assigned & Pending (by Team)					
Compliance Team	68	62	40	89	89
Drug Diversion/Fraud	85	70	72	90	90
Mediation Team	99	103	89	90	90
Probation/PRP	28	50	90	57	57
Enforcement	15	8	26	33	33
Application Investigations					
Initiated	37	10	5	45	97
Closed					
Approved	21	10	20	20	71
Denied	5	0	6	5	16
Total*	34	12	29	25	100
Pending (at the end of quarter)	46	53	25	29	29
Citation & Fine					
Issued	189	151	152	282	774
Citations Closed	153	137	134	80	504
Total Fines Collected	$56,236.00	$71,011.00	$83,386.00	$63,336.00	$273,969.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	49	34	16	33	132
Pleadings Filed	38	17	30	31	116
Pending					
Pre-accusation	64	76	60	50	50
Post Accusation	75	73	83	88	88
Total	160	161	152	145	145
Closed**	35	18	19	32	104
Revocation					
Pharmacist	4	1	4	3	12
Pharmacy	1	1	2	3	7
Other	11	8	7	13	39
Revocation,stayed; suspension/probation					
Pharmacist	9	4		1	14
Pharmacy	1				1
Other					0
Revocation,stayed; probation					
Pharmacist	5	2	1	2	10
Pharmacy	2				2
Other	1			1	2
Suspension, stayed; probation					
Pharmacist					0
Pharmacy					0
Other					0
Surrender/Voluntary Surrender					
Pharmacist	1	1	2		4
Pharmacy					0
Other	3	3	2	6	14
Public Reproval/Reprimand					
Pharmacist					0
Pharmacy	1				1
Other					0
Cost Recovery Requested	$120,408.25	$68,542.75	$127,302.00	$44,164.75	$360,417.75
Cost Recovery Collected	$46,386.35	$64,815.08	$19,523.99	$38,601.41	$169,326.83

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Probation Statistics					
Licenses on Probation					
Pharmacist	108	103	95	90	90
Pharmacy	16	14	11	4	4
Other	19	19	16	14	14
Probation Office Conferences	20	8	8	4	40
Probation Site Inspections	54	48	21	40	163
Probationers Referred to AG for non-compliance	3	3	0	1	7

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 06/30/06)

Program Statistics					
In lieu of discipline	1	1	0	0	2
In addition to probation	5	4	1	3	10
Closed, successful	0	0	5	0	5
Closed, non-compliant	3	0	0	0	3
Closed, other	0	0	1	3	1
Total Board mandated Participants	47	51	49	51	49
Total Self-Referred Participants*	16	16	23	23	23
Treatment Contracts Reviewed	40	40	46	42	126

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of June 30, 2006.

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 03/04	Total 04/05	Total 05/06
Complaints/Investigations			
Initiated	1491	1480	1697
Closed	2276	1985	1955
Pending (at the end of quarter)	683	655	633
Cases Assigned & Pending (by Team)			
Compliance Team	49	87	89
Drug Diversion/Fraud	61	89	90
Mediation Team	125	108	90
Probation/PRP	40	40	57
Enforcement	61	9	33
Application Investigations			
Initiated	140	129	97
Closed			
Approved	197	102	71
Denied	10	15	16
Total*	233	149	100
Pending (at the end of quarter)	35	39	29
Citation & Fine			
Issued	1589	754	774
Abated	1130	1004	504
Total Fines Collected	$880,232.00	$428,904.00	$273,969.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 03/04	Total 04/05	Total 05/06
Administrative Cases (by effective date of decision)			
Referred to AG's Office*	136	153	132
Pleadings Filed	106	95	116
Pending			
Pre-accusation	60	59	50
Post Accusation	75	77	88
Total	140	173	145
Closed**	123	111	104
Revocation			
Pharmacist	20	11	12
Pharmacy	5	4	7
Other	20	29	39
Revocation,stayed; suspension/probation			
Pharmacist	4	10	14
Pharmacy	0	0	1
Other	0	1	0
Revocation,stayed; probation			
Pharmacist	13	16	10
Pharmacy	2	3	2
Other	4	1	2
Suspension, stayed; probation			
Pharmacist	0	1	0
Pharmacy	0	0	0
Other	0	0	0
Surrender/Voluntary Surrender			
Pharmacist	9	5	4
Pharmacy	4	1	0
Other	8	14	14
Public Reproval/Reprimand			
Pharmacist	5	2	0
Pharmacy	1	0	1
Other	0	0	0
Cost Recovery Requested	$263,161.75	$393,282.00	$360,417.75
Cost Recovery Collected	$171,694.32	$169,422.50	$169,326.83

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Three Year Comparison

Workload Statistics	Total 03/04	Total 04/05	Total 05/06
Probation Statistics			
Licenses on Probation			
Pharmacist	113	103	90
Pharmacy	22	12	4
Other	22	23	14
Probation Office Conferences	31	33	40
Probation Site Inspections	127	153	163
Probationers Referred to AG for non-compliance	9	3	7

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of June 30, 2003)

Program Statistics			
In lieu of discipline	1	2	2
In addition to probation	10	16	10
Closed, successful	9	13	5
Closed, non-compliant	14	12	3
Closed, other	1	5	1
Total Board mandated Participants	50	46	49
Total Self-Referred Participants*	15	16	23
Treatment Contracts Reviewed	117	164	126

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of June 30, 2004.

California State Board of Pharmacy
Citation and Fine Statistics
July 1, 2005 – June 30, 2006

779 citations have been issued this fiscal year

Total dollar amount of fines issued
$ 845,312.00

Total dollar amount of fines collected
$ 164,100.00*

*This amount only reflects payment of the citations issued this fiscal year.
Citations issued prior to this fiscal year have also been paid during this time period.

The average number of days from date case is opened until a citation is issued is **146**

Average number of days from date citation is issued to date citation is closed is **48**

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
779	140	11	159	149	84	47	21	1

Miscellaneous Citation Breakdown by license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
67	52	5	2	6	16	10*	7	2

*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailer

Top Ten Violations for the first quarter of 2005/2006 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	43%	1716 - Variation from prescription	21%	1716 - Variation from prescription	10%
1716/1761 - Variation from Rx / Erroneous Rx	9%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	7.5%	4125/1711 - Quality assurance program	5.5%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	1716/1761 - Variation from Rx / Erroneous Rx	7.5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	2%	1715.6- Reporting drug loss	5%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	5%
4115(e) - Pharmacy technician license required	2%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	4081/1718 - Records of dangerous drugs kept open for inspection/Current inventory defined	5%
1793.7 -Requirements for Pharmacies employing pharmacy technicians	2%	4125/1711 - Quality assurance program	4%	1716/1761 - Variation from Rx / Erroneous Rx	3%
4071 - Prescriber may authorize agent to transmit prescription; Schedule II excluded	2%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	3%
1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	2%	4115(e) - Pharmacy technician license required	2%	1717(e) No licensee shall participate in any arrangement.., whereby medications may be left at, picked up from..., any place not licensed as a retail pharmacy.	3%
1301.11(a) - Persons Required to Register; Agents for Controlled Substances shall obtain DEA registration	1.5%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	1.6%	1717(f) – A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations § 1306.25...	3%
4081(a)- Records of dangerous drugs kept open for inspection	1.5%	1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	1.3%	4059.5(b) -A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board.	3%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were eighteen office conferences held so far this fiscal year

Number of requests	177
Number appeared	106*

Number scheduled	177
Number Postponed	48**

*Please note that on two occasions unscheduled pharmacy citations were also heard at office conference.
**Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	24
Failed to appear	7

Office Conference results

Total number of citations affirmed	54

Decision	Total citations	Total dollar amount reduced
Modified	29	$22,750.00
Dismissed	31	$1,875.00
Reduced to Letter of Admonishment	4*	$0.00

*All citations reduced to Letter of Admonishment, were citations issued without a fine

ATTACHMENT I

Strategic Plan Status Report
Fourth Quarter 2005/2006
April 1, 2006 through June 30, 2006

Enforcement Committee

Goal 1: **Exercise oversight on all pharmacy activities**

Outcome: **Improve consumer protection**

Objective 1.1: **To achieve 100 percent closure on all cases within 6 months by June 30, 2006.**

Measure: Percentage of cases closed or referred within 6 months.

Task:

1. Mediate all consumer complaints within 90 days.

Quarter 1: Based on **211** mediations/investigations sent to Supervising Inspectors for review.
Quarter 2: Based on **239** mediations/investigations sent to Supervising Inspectors for review.
Quarter 3: Based on **283** mediations/investigations sent to Supervising Inspectors for review.
Quarter 4: Based on **239** mediations/investigations sent to Supervising Inspectors for review.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 90	24	11%	35	15%	8	3%	**42**	**16%**
91 to 180	11	5%	30	12%	18	6%	**23**	**9%**
181 to 365	1	0%	5	2%	28	10%	**2**	**1%**
366 and over	1	0%	0	0%	6	1%	**0**	**0%**

2. Investigate all other cases within 120 days.

Review total stats same as above

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 120	106	50%	77	32%	131	46%	**120**	**46%**
121 to 365	63	30%	89	37%	91	32%	**70**	**27%**
366 and over	5	2%	3	1%	1	1%	**4**	**1%**

Task:

3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Quarter 1: Based on **550** closed mediations/investigations.
Quarter 2: Based on **421** closed mediations/investigations.
Quarter 3: Based on **439** closed mediations/investigations.
Quarter 4: Based on **441** closed mediations/investigations.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 180	405	74%	303	72%	244	56%	**324**	**73%**
181 to 365	123	22%	106	25%	164	37%	**100**	**23%**
366 to 730	18	3%	11	3%	30	7%	**16**	**4%**
731 and over	4	1%	0	0	1	0%	**1**	**0%**

Task:	**4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.** **First, Second, Third & Fourth Quarters:** Nothing to report.
Task:	**5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).** **CURES** **Number of pharmacies reporting to CURES and number of prescription records reported.** Quarter 1: 5,044 2,799,811 Quarter 2: 5,680 3,440,267 Quarter 3: 5,212 3,239,285 **Quarter 4: 5,347 4,828,988** **CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:** Quarter 1: 15 Quarter 2: 23 Quarter 3: 9 **Quarter 4: 14** **CURES data used in complaint investigations:** Quarter 1: 20 Quarter 2: 8 Quarter 3: 0 **Quarter 4: 8** **CURES compliance issues found in inspections:** Quarter 1: 10 Quarter 2: 25 Quarter 3: 8 **Quarter 4: 22** **1782 Wholesaler Data Base:** No changes. Board has not been using 1782 reports for the last 3 to 4 years. **DEA 106 Theft/Loss :** Quarter 1: Approximately 42 investigations opened from DEA 106 loss reports. Quarter 2: Approximately 37 investigations opened from DEA 106 loss reports. Quarter 3: Approximately 88 investigations opened from DEA 106 loss reports. **Quarter 4:** Approximately **54** investigations opened from DEA 106 loss reports.
Task:	**6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.** ▪ The CURES Users Group is scheduled to meet the 2nd Wednesday of every month to

work on pharmacy noncompliance and data issues, share case information, as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151 and more recently, SB734, as well as new federal NASPER regulations.

BNE canceled the October meetings due to database issues. We do not meet in December.

First Quarter: During a recent driver upgrade to the new CURES web-based database, the BNE encountered a corruption to the front end portion of the database. The front end is the part of the database that allows users the ability to run standard and ad hoc queries and reports. None of the data was lost, only lost query and report functionality. While BNE is fixing the web-based system, they have temporarily reinstated the previous Impromptu CURES database to allow users access to the data and the ability to run queries and reports.

Second Quarter: The BNE completed repairs to the Web-based CURES system in December 2005. Board staff can now access CURES data through both the old and the new applications. BNE information technology staff are working with board staff to develop several automated standard reports using the new Web-based system's report-scheduling functionality, which will save staff time and provide monthly or weekly statistical and trend data via email automatically. Board staff is learning to use the new Web-based ad hoc reporting capabilities and will begin rebuilding CURES reports used regularly by the board for investigations and non-compliance. Reports that board staff developed in the old CURES database cannot be used on the new Web-based system. In the interim, the BNE is allowing access to CURES data through the old software to access the board's reports.

BNE has applied for federal grant money to fund additional improvements to CURES and allow BNE to meet new federal regulations (NASPER), such as capturing method of payment, and the legal identification of the patient or person picking up the controlled substance in CURES, the addition of Schedule IV controlled substance reporting and weekly reporting, etc. The DOJ is also studying ways to automate the process for physicians and pharmacists to request a patient activity report (PAR) from CURES. This will be especially useful for emergency room physicians and pharmacists. DOJ is also working on an automated reporting tool for direct dispensing physicians.

Third Quarter: The BNE continues working with board staff on developing standard CURES reports and data look-up functions. The BNE continues to study ways to automate CURES processes and implement NASPER federal requirements. Additionally, the BNE is working on the core language for the request for proposal (RFP) to conduct a feasibility study on real-time reporting to CURES and real-time data access to prescribers and pharmacists. Once the board receives this core language, staff will prepare the RFP and facilitate the proposal process.

Fourth Quarter: In June, the BNE completed and submitted to the board a draft scope of work and is working with board staff to prepare a request for proposal to conduct a feasibility study of real-time reporting by pharmacies to CURES and real-time access to CURES by authorized prescribers as required by Health and Safety Code section 11165.5.

The BNE continues working with board staff on developing standard CURES reports and data look-up functions. The BNE continues to study ways to automate CURES processes and implement NASPER federal requirements.

	Each Quarter: An inspector and a supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.
Task:	**7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.** First, Second, Third and Fourth Quarters: Nothing to report.
Task:	**8. Improve public service of the Consumer Inquiry and Complaint Unit.** First Quarter: ▪ Three new informational flyers were developed through UCSF addressing the issues of recalled medication, generic medication, and cutting drug costs. ▪ "What You Should Know Before Buying Drugs from Foreign Countries or the Internet" and "Tips to Save You Money When Buying Prescription Drugs", are now available in Chinese, Vietnamese, Spanish, and English languages. ▪ The board now has 24 consumer brochures and publications, including Health Notes. ▪ Board staff provided consumer information at the City of Sacramento Public Safety Center's Community Celebration on September 24, 2005. ▪ Board staff provided consumer information at the UCD Healthy Aging Summit on October 15, 2005. Second Quarter: ▪ Nothing to report this quarter. However, several events are scheduled for next quarter. Third Quarter: ▪ Six new informational flyers were developed through UCSF addressing the issues of double dosing, taking herbal medication, missing doses, Diabetes, disposing of medications, and oral health. ▪ Board staff developed 4 new consumer brochure: Easier to Read Prescription Drug Information; Children and Their Medications; Do You Sometimes Forget to Take Your Medications; and Medicare Part D. ▪ Board staff are revising several consumer brochures and fact sheets. **Fourth Quarter:** ▪ Board staff revised 2 informational flyers developed to address the issues of How Alcohol Can React With Medications, and How and When Do I Talk About My Prescriptions? ▪ Board staff revised 5 consumer brochures: 14 Reasons to Talk to your Pharmacist, Reasons to Talk to your Pharmacist about your Child's Medication, Get the Answers, Facts about Older Adults & Medicines, Do you have a Complaint, and How to Take your Pain Medications Effectively and Safely. ▪ Board staff revised the California Board of Pharmacy Board Member Procedure Manual. ▪ Board staff provided informational materials at 3 consumer events this quarter: Family Safety & Health Expo in Sacramento on 5/13; Senior Services Fair in Yreka on 5/17; and the City of Sacramento Wellness Expo on 5/11.
	9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. **Investigative Activities:**

First Quarter:

- With the addition of Schedule III prescriptions added to the CURES database, the volume of data has grown too large to transmit to the inspectors via email. Staff developed a program to put on CD for each inspector that will automatically install an updated CURES data file to their laptops with the click of a button. CD's with updated CURES data files are mailed monthly to each inspector.
- To improve case management efforts, a monthly report is prepared and submitted to management. This report reflects the age of the case, who the case is assigned to, which cases are under review with the Supervising Inspector, cases that are referred to citation and fine and/or the Attorney General. The report identifies those cases not currently assigned. The report is also used as a tool to identify and locate those cases that have not had any recent activity.
- The department is currently evaluating tools to implement ad hoc reporting. through the Enforcement Users Group meetings the latest information is that they are in the selection process and hope to be able to test the product soon. All vendor demonstrations are complete. The selection has not been announced. OIS has met with the Chief Information Officer and Project Executive Sponsor to discuss findings. The CIO and PES will determine what further action will be taken.
- Staff performed various updates to improve functionality of the various enforcement databases.

Second Quarter: Nothing to report

Third Quarter:

- Staff performed ongoing improvements to Case Action Summary. Installed in March 2006.
- Staff developed instructional computer video clips - WinZip, Word, Excel, Expense Report, Screen Print, and Acrobat
- Staff indexed the 2006 Law Book
- Staff configured Supervisor Desktop Computers
- Staff and OIS installed encryption software on all laptops.

Fourth Quarter:

- Board staff built a database documenting all of the various Access databases used and developed by the board. The database describes each database in detail including its purpose, provides file directory locations, lists all related tables, lists the reports available, and provides other critical information.
- Board staff tested Virtual Private Network (VPN connectivity on 2 inspector laptops. VPN connectivity allows for a highly secure connection through high speed internet DSL or cable connectivity. VPN dramatically improves the speed in which the inspectors transmit and receive data using their laptops. Board staff will begin rolling out VPN to all inspectors over the next few months.

Inspection Activities – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include:

First Quarter:

- Color coding queries showing licensees that have already been scheduled for inspection, need to be scheduled for inspection, and those inspections completed had to be updated with new criteria now that the new 4 year inspection cycle has started.
- Revised wholesale and LSC automated reports to include assignment information.
- 75 security printers are currently approved to produce controlled substance prescription forms. Ten of the approved printers utilize the services of several hundred distributors that market their prescription products to prescribers.

Second Quarter:

- Staff developed a tool to print case action summaries.
- Staff developed a Probation / PRP database for staff and field inspectors. The system has been in the test mode for 3 months. Data entry of all participants and scanning of relevant documents is in the process.
- Staff set up and trained new inspectors on computers, cell phones, and GPS.
- CURES data is extracted monthly and integrated into the Inspector Data program allowing the Inspectors to view the total number of prescriptions by drug for a specific pharmacy during a three-month rolling cycle. Each month staff prepares a CD that contains a list of over 13, 000 inspection reports that can be viewed and printed; all active board-licensed California sites and licensees; DEA 106 list of scanned DEA 106 forms; and the CURES data file. The CD also provides other updates, when applicable, such as new issues of The Script and the new Pharmacy Law Book.
- Ongoing improvements to the Inspector Data and Inspector Activity installed in November 2005 and December 2006.
- Report functionality improvements to the Evidence database.
- Ongoing functionality and report capability improvements to the inspection assignment program.
- Staff copied inspector laptop data files and compared laptop Access data tables to the data tables on the server and made adjustments. Staff also generated missing inspection reports from inspector laptop files in electronic format and added to the server.
- SB734 transfers the application process for security printer approval to the Department of Justice January 1, 2006. Staff made changes to the database to provide greater functionality and ease in data entry before sending it to the DOJ. The board had approved 79 security printers as of January 1, 2006.

Third Quarter:

- Ongoing improvements to Inspector Data and Inspector Activity. Updates installed in March 2006. Added function to print receipts for a complainant.
- Ongoing improvements to Assignment program function and reporting.
- Major changes to Inspector Probation Program - fixed transmission issues, added ability for multiple assignments for the same Participant, and added ability to type enter Interview forms.
- Monthly CD is sent to all inspectors and supervising inspectors with the following updated information:
  - View Word file - list of over 13,000 inspection reports that can be viewed/printed if connected to server
  - Teale Licensing File - all active licensed California business and licensees
  - CURES Data file - approximately 150,000 records per 3-month period.
    - Contains summarized data for a pharmacy
  - DEA 106 file - list of scanned DEA 106 Theft or Loss forms received can be viewed if online

Fourth Quarter:

- Several improvements to functionality were implemented to the inspector activity, inspector data, and probation/PRP databases.
- Board staff developed a licensee search tool that searches inspection reports by licensee name, personal license number or pharmacy license number.
- Monthly CD was sent to all inspectors and supervising inspectors with updated inspection and CURES data files.
- Board staff developed a report database specifically for supervising inspectors to track inspection assignments, data transmission dates, and inspector activity data.

Objective 1.2	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2006.** **Measure:** Percentage closure on administrative cases within one year.
Task:	1. **Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.** ▪ First Quarter: DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate. ▪ Second Quarter: Nothing to report. ▪ Third Quarter: DAG rates will increase to $158 per hour and paralegal rates will increase to $101 per hour effective July 1, 2006. ▪ **Fourth Quarter**: The new DAG and paralegal rates became effective July 1, 2006.
Task:	2. **Aggressively manage cases, draft accusations and stipulations, and monitor AG billings and case costs.** ▪ Case management and review of pending cases is a continuous process.

	Q1	Q2	Q3	Q4
Status memos sent to AG	35	24	10	**3**
Disciplinary Cases Closed:				
0-365 days	21	11	11	**14**
366 + days	21	11	10	**18**
Accusations reviewed	39	25	36	**34**
Accusations needing revision	7	3	6	**5**
Accusations filed	38	17	30	**31**
Stips/proposed decisions reviewed	15	19	14	**14**
Cases reviewed for costs	10	8	7	**8**

Task:	3. **Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.** **First, Second, Third, & Fourth Quarters**: Nothing to report.
Task:	4. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** ▪ Administrative Case Management Database Program: First, Second, & Third Quarters: No changes. **Fourth Quarter**: Board staff updated DOJ costs to reflect changes effective 7/1/06.

Objective 1.3:	**Inspect 100 percent of all licensed facilities once every 3 to 4 years by June 30, 2009.** **Measure:** Percentage of licensed facilities inspected once every 3 years.
Task:	**1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** ▪ For all quarters, see response to Objective 1.1, Task #9
Task:	**2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.** **Inspection Statistics Background:** First Quarter: On July 1, 2005, the board began its second 3 to 4-year cycle of inspections towards the goal of inspecting all sites once every 3 to 4 years (by June 30, 2009): ▪ Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,735**; · Total number of inspections completed **611**, · Total number of inspections to be completed by June 30, 2009 are **7,119 or 7.9%**. ▪ Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,915**; · Total number of inspections completed **618** or **7.8%.** · Total number of inspections to be completed are **7,292** *inspection data as of 10/1/05 Second Quarter: ▪ Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,670**; · Total number of inspections completed **1.202 or 15.67%;** · Total number of inspections to be completed by June 30, 2009 are **6,464.** ▪ Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,947**; · Total number of inspections completed **1,227** or **15.44%;** · Total number of inspections to be completed are **6,716.** *inspection data as of 1/1/06 Third Quarter: ▪ Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,583**; · Total number of inspections completed **1,671 or 22.04%;** · Total number of inspections to be completed by June 30, 2009 are **5,908.** ▪ Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,993**; · Total number of inspections completed **1,739 or 21.76%;** · Total number of inspections to be completed are **6,250.** *inspection data as of 4/3/06

Fourth Quarter:

- Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,465.**
  - Total number of inspections completed **2,200 or 29.47%**
  - Total number of inspections to be completed by June 30, 2009 are **5,261.**

- Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **8,570.**
  - Total number of inspections completed **2,309 or 26.94%**
  - Total number of inspections to be completed are **6,257.**

*inspection data as of 4/3/06

Total Number	Q1	Q2	Q3	Q4
Inspections Completed	710	568	807	**808**
Routines/ Wholesaler-Vet-Retailer/ Probation/PRP	584	463	723	**676**
Sterile Compounding *(included in routines)*	79	36	46	**77**
Investigation Inspections	126	105	142	**132**
Status 3 *(included in routines)*	4	9	7	**14**
Routine resulting in complaint investigation. (included above)	34	14	26	**34**

Wholesaler/Vet Retailer Inspection Program – The board implemented the Wholesaler Inspection Program beginning March 1, 2005. Data are included in the previous table and shown separately here for reference only.

A total of **506** sites identified for inspection.

- As of September 30, 2005, the Diversion Team has completed a total of 239 inspections since program inception.
- As of January 1, 2006, the Diversion Team has completed a total of 285 inspections since program inception.
- As of April 1, 2006, the Diversion Team has completed a total of 304 inspections since program inception.
- As of July 1, 2006, the Diversion Team has completed a total of **362** inspections since program inception.

	Q1	Q2	Q3	Q4
Wholesaler/Vet Retailer Inspections Completed *	95	52	87	**51**

* Includes routine, call backs, and CI inspections.

Task:

3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities

First, Second, Third, & Fourth Quarters: Nothing to report.

Objective 1.4	**Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2006.** **Measure:** Number of communication venues (excluding inspection program)
Task:	**1. Develop the board's website as the primary board-to-licensee source of information.** ▪ Public disclosure of disciplinary history on licensees is online. First Quarter Web Additions/Revisions ▪ Posted board meeting dates for 2006 ▪ Posted board and committee information - agenda, materials & minutes ▪ Regulation updates ▪ Updated several application packets ▪ Added new version of self-assessment forms ▪ Created a page on Hurricane Katrina Information and Resources ▪ Added newly approved Security Printers (total 77) ▪ Updated the Script Newsletter Index ▪ Sent out subscriber alert notifications to the board's e-mail notification list Second Quarter Web Additions/Revisions: ▪ Updated all Web pages with the board's new address and phone numbers. ▪ Added bond information to applications. ▪ Sent subscriber alerts. ▪ Update the regulation and legislation Web pages. ▪ Posted board and committee meeting agendas and materials. ▪ Updated the strategic plan. ▪ Revised the security printer Web page to link to the DOJ. ▪ Added the revised community, hospital, and sterile compounding self-assessment forms. Third Quarter Web Additions/Revisions: ▪ Updated security printer information and links ▪ Updated instructions for some of the application packets ▪ Updated the law book ▪ Updated CPJE regrade information ▪ Added the new The Script newsletter ▪ Added Appstatus@dca.ca.gov email address for Pharmacy Tech applicants to check status of their application. ▪ Corrected law book contents ▪ Added contact information to the website ▪ Posted board and committee meeting agendas and materials ▪ Sent out subscriber alert notifications to the board's e-mail notification list **Fourth Quarter Web Additions/Revisions:** ▪ Updated instructions for some of the application packets. ▪ Added information about purchasing the law book. ▪ Updated number of regrades. ▪ Corrected search function. ▪ Updated Board Member information. ▪ Updated CE requirements. ▪ Added Enforcement Actions to website. ▪ Posted board and committee meeting agendas and materials. ▪ Sent out subscriber alert notifications to the board's e-mail notification list.

Task:	**2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.** ▪ January 2005 *The Script* Newsletter published. ▪ October 2005 *The Script* Newsletter published. ▪ January 2006 *The Script* Newsletter published. ▪ The next *The Script* Newsletter is scheduled to be published in July 2006.
Task:	**3. Update pharmacy self-assessment annually.** First Quarter: Revised form so that fields can be filled in online. New version posted of the web. ▪ Regulation requiring 2005 version took effect 10/7/05. Second Quarter: Board approved the wholesale self-assessment October 2005 and recommends moving ahead with regulations to require wholesalers to complete a self-assessment every 2 years. Third Quarter: Nothing to report **Fourth Quarter**: Nothing to report.
Task:	**4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.** First Quarter CE Presentations ▪ Supervising Inspector Nurse presented information about the board and how it investigates cases to a group of United States Attorneys on July 20. ▪ Supervising Inspector Nurse participated in a training module for federal investigators who will be monitoring fraud in the Medicare Prescription Drug Plan programs in San Diego on September 20. ▪ The board staffed a public information booth the City of Sacramento Public Safety Public Fair on September 24. ▪ The board will staff a public information booth on October 15 at the UCD Healthy Aging Fair. ▪ Supervising Inspector Ratcliff will present information on pharmacy law changes at a UFCW-Orange County Pharmacist Association continuing education conference on October 16. ▪ The board will staff an information booth at CSHP Seminar on October 21 and 22. ▪ Several board members will present information at this association meeting. ▪ Supervising Inspector Ming will present information about pharmacy law to a group of UCSD pharmacy students in mid-November ▪ Assistant Executive Officer Herold will present information about the board to a group of UCSD pharmacy students on November 28. ▪ Supervising Inspector Ming will present information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30. ▪ Board Member Jones will present information about pharmacy technology at the NABP Fall Conference in December. Second Quarter CE Presentations: ▪ Supervising Inspector Nurse participated as the board's representative to the Northern California Pain Initiative on January 9. ▪ Board President Goldenberg participated on an NABP Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy

Management Provisions conference call on October 27.

- Board President Goldenberg was keynote speaker at a conference of long-term care executives on Medicare Part D in Los Angeles on November 4.
- Supervising Inspector Ming presented information about pharmacy law and board pharmacy inspections to a group of UCSD pharmacy students on November 14.
- Assistant Executive Officer Herold presented information about the board to a group of UCSD pharmacy students on November 28.
- Supervising Inspector Ming presented information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30.
- Board Member Jones presented information about pharmacy technology at the NABP Fall Conference in Florida on December 4.
- Board Member Fong presented information about new pharmacy laws to pharmacists at the Diablo Valley Pharmacists Association Meeting on December 28.
- Supervising Inspector Ratcliff presented information to the California State University Pharmacists on current law topics on January 12.
- Board President Goldenberg and Supervising Inspector Ratcliff presented information about the board and new pharmacy law on January 19 to USC students.

Third Quarter CE Presentations:

- Executive Officer Harris participated as a speaker during the Federation of Associations of Regulatory Boards annual meeting in early February, as part of a panel discussion on "Board Governance: A Panel Discussion on the Pros and Cons of Different Board Structures" on February 3. She also participated in a panel discussion on February 5 on alternative enforcement models.
- Executive Officer Harris and Analyst Sue Durst staffed an information booth at the San Diego Consumer Protection Day fair on February 3; approximately 1,500 people attended.
- Supervising Inspector Nurse provided a PowerPoint presentation via teleconference to an FDA Counterfeiting Task Force in Bethesda, MD, on February 9.
- The board staffed an information booth at the CPhA Outlook Meeting on February 17 and 18.
- Supervising Inspector Ming and Exam Analyst Debbie Anderson provided law and examination information to 80 Western Pharmacy School students on February 24.
- Supervising Inspector Ratcliff provided information about pharmacy law to 125 students at UCSF on February 28.
- Board Member Ruth Conroy spoke to 50 Touro University pharmacy students on board legislative issues on March 31.
- Supervising Inspector Ming presented law review information to UCSF's 4th year students on April 7.
- Board President Goldenberg provided welcoming remarks to the opening session of the National Association of Boards of Pharmacy Annual Meeting in San Francisco. Other board presentations at this annual meeting included moderation of a panel discussion by Executive Officer Harris on emergency preparedness and a poster session on the Notice to Consumers that must be displayed in pharmacies.

Fourth Quarter CE Presentations:

- Board Member Ruth Conroy spoke to about 50 Touro University pharmacy students on board legislative issues on March 31, as preparation for their Legislative Day in April.
- Supervising Inspector Ming presented law review information to UCSF's 4th year students on April 7.
- Supervising Inspector Ming presented information about pharmacy law to approximately 30 UCSF and UOP students at Anaheim Memorial Hospital on April 28.
- Staff hosted an information booth at the City of Sacramento Wellness Expo 2006 in Sacramento, about 300 individuals attended this event on May 11.
- Executive Officer Harris spoke at the Department of Consumer Affairs Senior Summit on May 12 in Sacramento on "Protecting and Serving California's Aging Population."

	Staff also provided handout packets containing board-prepared public information brochures. ▪ Staff hosted an information booth at the Family Safety and Health Expo (Safetyville) in Sacramento on May 13 where over 700 individuals attended. ▪ Exam Analyst Debbie Anderson presented information about examination application to Loma Linda University's pharmacy students on May 15. ▪ Staff hosted an information booth at the Senior Fair sponsored by the Area Agency on Aging in Yreka on May 17. There were approximately 200 seniors at this event. ▪ Board President Goldenberg and Member Conroy provided information about the board to UOP students on May 18. ▪ Patricia Harris presented information about quality assurance programs to the SCR Prescription Error Study Panel on May 19. ▪ Patricia Harris presented a PowerPoint presentation on prescription errors and the board's cite and fine program to the SCR 49 Prescription Error Study Panel on June 9. (She later presented this information at the board's Enforcement Meeting on June 20 and some of the presentation will be published in the next The Script.) ▪ Supervising Inspector Ratcliff presented information about pharmacy law to the 80 members of the California Employee Pharmacists Association on June 11. **Future Presentations** ▪ Supervising Inspector Ratcliff will present information about the board and pharmacy law to the Sacramento Valley Pharmacist Association on August 13. ▪ Supervising Inspector Ratcliff will present information about pharmacy law to 80 members of the California Employees Pharmacist Association on September 28.
Task:	**5. Hold quarterly Enforcement Committee Meetings** First Quarter: ▪ Meeting held June 2005. Discussed importation, use of automated devices in clinics. Interpretation of pharmacy law related to Interns, waiver requests for self-use automated delivery systems, and petitions for consideration. ▪ Meeting held September 2005. Discussed importation, disciplinary guidelines, self assessment for wholesalers, legibility of prescriptions, DEA requirements for prescribing Schedule II drugs, new labeling requirements, and electronic pedigree requirements. Second Quarter: ▪ Meeting held in December 2005. Discussed implementation of pedigree requirement, faxed prescription form patients, generic substitution by prescriber on electronic data transmission prescriptions, citation and fine program, GAO report on anabolic steroid without prescription, and importation of prescription drugs. Third Quarter: ▪ Meeting held in March 2006. Discussed implementation of E-pedigree requirements, E-pedigree standards, and E-pedigree pilot programs. Facilitated an E-pedigree questions and answers session, and discussed request to extend E-pedigree implementation to January 2008. **Fourth Quarter:** ▪ Meeting held in June 2006. Reviewed the Board's Strategic Plan – discussed enforcement goal and strategic objectives for 2006 through 2011. Presentation on prescription error data from 1999 through 2006. Discussion regarding new Federal requirements regarding the sale of Pseudoephedrine and Ephedrine –containing products. Report from the California Pedigree Working Group.

Objective 1.5	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2006.** **Measure:** Percentage compliance with program requirements

Task:

1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).

Pharmacists Recovery Program	**Q1**	**Q2**	**Q3**	**Q4**
Total # of PRP Participants	63	67	72	**74**
Number Referred to PRP	6	5	1	**3**
Number Closed from PRP	4	0	6	**3**
Probation Monitoring Program - Number on Probation	**Q1**	**Q2**	**Q3**	**Q4**
Pharmacists	108	103	95	**90**
Pharmacies	16	14	11	**4**
Other	19	19	16	**14**
Citation and Fine	**Q1**	**Q2**	**Q3**	**Q4**
Citations Issued	189	151	152	**282**
Fines Collected	$56,236	$71,011	$83,386	**$63,336**

Task:

2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

First Quarter: Currently in the process of establishing a database for the Citation and Fine unit. The database will automate the processes of creating letters, memos and statistics, which are currently completed by staff manually.

- Working with staff in linking databases
- Working with OIS to automatically receive monthly licensure information
- Working with Citation and Fine unit to verify needs for letters and memos
- Testing for integrity of statistical data.

Second Quarter: No changes.

Third Quarter: No changes.

Fourth Quarter: No changes.

Objective 1.6	**Respond to 95 percent of all public information requests within 10 days by June 30, 2006.** **Measure:** Percentage response to public information requests within 10 days.
Task:	**1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.** ▪ Web Enforcement Look-Up – In production May 2004. Completed disciplinary actions are entered into the database on an on-going basis. ▪ Staff has begun scanning public disciplinary documents for availability as a PDF document on the Web Enforcement Look Up. ▪ March 2006 - Public documents from 2001 to current are now available for download into PDF format online. ▪ July 2006 – The board will implement a new enforcement action webpage. By using this feature you can see which licensees have had discipline taken against their license during specific time periods. The page willcontains the last year of action and will continue to grow until the last three years are represented.
Task:	**2. Establish on-line address of record information on all board licensees-** ▪ Licensee address of record information became available on-line to public in December 2003. – Regulation to ban posting on Website the address of record of intern pharmacists goes to the board for adoption. If approved, the rulemaking files will be submitted to the Administration for approval in November 2005. – Regulations are anticipated to go into effect in the summer of 2006.
Task:	**3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.**

Total by Type of Requests Received				
Request Type	**Q1**	**Q2**	**Q3**	Q4
Public	30	17	27	**15**
Licensees	24	7	9	**4**
Other agencies	29	34	43	**46**
License Verifications	223	200	138	**229**

Time Frame Records Requests Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
	Number and Percentage Per Quarter							
Within 10 days	67	81%	38	66%	49	62%	**38**	**58%**
Over 10 days	16	19%	20	34%	30	38%	**27**	**42%**
Time Frame License Verifications Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
	Number and Percentage Per Quarter							
Within 10 days	210	94%	176	88%	126	91%	**167**	**73%**
Over 10 days	13	6%	24	12%	12	9%	**62**	**27%**

Objective 1.7	**Initiate policy review of 25 emerging enforcement issues by June 30, 2006.** **Measure**: The number of issues.
Tasks (Issues)	1. Reimportation of drugs from Canada. ▪ Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and board meeting. ▪ January 2005: Discussed at Board Meeting. ▪ March 2005: Discussed at Enforcement Committee Meeting. ▪ April 2005: Discussed at Board Meeting. ▪ May 2005: Discussed at Enforcement Committee Meeting. ▪ July 2005: Discussed at Board Meeting. ▪ September 2005: Discussed at Enforcement Committee Meeting. ▪ October 2005: Discussed at Board Meeting ▪ December 2005: Discussed at Enforcement Committee Meeting ▪ February 2006: Discussed at Board Meeting 2. Modification to the Quality Assurance Regulation regarding patient notification. (completed) 3. Proposals regarding wholesale transactions. ▪ Sponsored legislation (SB 1307). ▪ January 2005 – SB 1307 became effective. ▪ January 2005– Participated in NABP Task Force to develop e-pedigree elements. ▪ January 2005 – Participated in NABP Wholesaler's Distributors Regulatory meeting and participated in NABP Task Force to develop e-pedigree elements. ▪ February 2005 –Implementation of SB 1307. ▪ April 2005– Presentation to board on pedigree software ▪ June 2005 – two presentations to Enforcement Committee on pedigree software. ▪ September 2005– discussed at the Enforcement Committee Meeting regarding the difficulty of implementation. ▪ November 2005: Recommend legislation clean-up language for 2006. ▪ December 2005: Developed Q & A for implementation discussion at the Enforcement Committee Meeting. ▪ February 2006: Board agreed to form workgroup to discuss implementation ▪ March 2006: First workgroup meeting held with over 65 participants. ▪ April 2006 – Staff attended California Pedigree Working Group (CPWG) meeting ▪ April 2006 – Discussed CPWG meeting at the April Board meeting. Presentation by EPCglobal on the status of setting standards for electronic pedigree. ▪ May 2006 – Staff attended second CPWG meeting. ▪ June 2006 – Staff attended third CPWG meeting. 4. Clarification regarding prescription records by authorized officers of the law. ▪ October 2005: updated article in the board's newsletter. 5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present. ▪ Sponsored legislation SB 1913 ▪ January 2005– bill passed, SB 1913 effective 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). ▪ DOJ and board approved for controlled substances. 7. Prescriber dispensing. ▪ May 2003 - Workgroup with Medical Board on proposal on prescriber dispensing by physician groups. 8. Implementation of federal HIPAA requirements. 9. Prohibition of pharmacy-related signage. 10. Implementation of enforcement provisions from SB 361. 11. Implementation of SB 151 (elimination of the Triplicate).

- January 2005 – new changes to controlled substance law took effect. Continued CE presentations.
- February 2005 – continued CE presentations
- March 2005 – discussed Q & A at Enforcement Committee meeting.
- April 2005 – discussed at board meeting.
- June 2005 – discussed at Enforcement Committee meeting.

12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.
17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology
    - Statutory change (SB 1913), regulation proposal to implement.
    - October 2005 - Regulation became effective.
21. Update of pharmacy laws related to PRP.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
22. Update of pharmacy law related to pharmacy technicians.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
23. Clean-up of "Letter of Admonishment" provision.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
24. Use of "kiosks: for drop-off of prescriptions.
    - October 2005– board approved waiver for kiosks and regulation change
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
    - February 2006: Board approved revised language and moved to regulation hearing.
    - April 2006 – Board adopted regulation.
25. Use of self-services dispensing units for pick-up of refill prescriptions.
    - October 2004– board approved statutory changes
    - January 2005– board approved second waiver
    - April 2005 – board approved third waiver in conjunction with a study.
    - June 2005– request to require "Pharmacy Service Plans" for approved waiver.
    - July 2005Board approved two more waivers.
    - Overview of study by UCSD presented.
    - September 2005 - Regulation change noticed.
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
    - February 2006: Board approved revised language and moved to regulation hearing.
    - April 2006 – Board adopted regulation.
26. Mandatory reporting of impaired licensees.
    - January 2005–board approved statutory change
    - March 2005 - SB 1111 introduced
    - January 2006: Statutory change (SB111) became effective.

- March 2006 – Provisions need to be corrected and added to SB 1475.

27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.
    - March 2005 – Discussed at Enforcement Committee meeting – no action necessary.
28. Prescribing Authority for Naturopathic Doctors
    - February 2005 – Met with Bureau of Naturopathic Doctors and other interested parties regarding proposed legislative changes to address inconsistencies in pharmacy law.
    - February 2005 – Requested legal opinion from DCA.
    - April 2005 -Opinion provided to Board.
    - June 2005 -Clean-up statutory provisions introduced in bill.
    - December 2006: Requested presentation from Naturopathic Doctor on profession practices.
29. Pharmacy law clarification regarding pharmacist interns, orally and electronically transmitted prescriptions, and filling on non-security Rx form for controlled substances. (June 2005)
30. Use of automated drug delivery systems in clinics. (June 2005)
    - July 2005: Board clarified use of systems
31. Request to repeal CCR 1717.2.
    - July 2005 Board approved – Referred to Legislation and Regulation Committee.
32. Legal requirements and process for Petitions for Reconsideration. (June 2005)
    - July 2005: Board reaffirms the process for petition for reconsideration.
33. Proposed self-assessment for wholesalers. (September 2005)
    - October 2005: Board approved proposed regulation to implement self-assessment form for wholesalers – Referred to Legislation and Regulation Committee.
34. Legibility of prescription – Refer to SCR49 Medication Error Panel for review. (Sep 2005)
35. Revised self-assessment for pharmacies.
    - October 2005 - Regulation became effective.
36. Update regulation 1745 regarding the partial fill of Schedule II prescriptions.
    - October 2005 - Regulation change became effective.
37. Proposal to amend B & P Code section 4040 (c) to allow a pharmacy to accept a fax prescription from a patient.
    - December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board.
    - February 2006: Pharmacy can accept a faxed prescription from a patient but cannot dispense the medication until the prescription is received. No law change is necessary.
38. Proposal to amend B & P 4073(b) to indicate the prohibition on generic substitution by a prescriber on an "electronic data transmission" prescription.
    - December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board.
    - February 2006: Board approved. Will be added to Omnibus bill.
39. Reviewed citation and fine program at the request of California Retailers Association
    - September 2005: Noticed on agenda and provided 3-year data on program – no comments were received.
    - December 2005: Noticed on agenda and provided 3-year data on program – no comments were received.
40. Revised Disciplinary Guidelines
    - September 2005: Discussed at Enforcement Committee Meeting
    - October 2005: Board approved the changes for a proposed amendments to the regulation – referred to the Legislation and Regulation Committee.
41. Implementation of federal requirements regarding the sale of pseudoephedrine ad ephedrine containing products.
    - June 2006 – Discussed at Enforcement Committee Meeting.
42. Prescription Error Complaint Data
    - June 2006 – Presented at the SCR 49 (Prescription Error Panel) and the Enforcement Committee Meeting prescription error complaint data from 1999 to 2006.